"A COMPARATIVE STUDY OF CHEMICAL SPHINCTEROTOMY (USING 2% DILTIAZEM) AND LATERAL INTERNAL SPHINCTEROTOMY FOR CHRONIC ANAL FISSURE"

A DISSERTATION SUBMITTED TO THE TAMILNADU

DR MGR MEDICAL UNIVERSITY

CHENNAI

In partial fulfillment of the requirement for the degree of

M.S. (GENERAL SURGERY)

BRANCH - I

DEPARTMENT OF GENERAL SURGERY

TIRUNELVELI MEDICAL COLLEGE

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I hereby declare that the dissertation titled **"A COMPARATIVE STUDY OF CHEMICAL SPHINCTEROTOMY (USING 2% DILTIAZEM) AND LATERAL INTERNAL SPHINCTEROTOMY FOR CHRONIC ANAL FISSURE"** is a bonafide and genuine research work carried out by me at Tirunelveli Medical College Hospital, Tirunelveli under the guidance of Dr.M.S.VARADARAJAN M.S., HOD & Professor, Department of General Surgery, Tirunelveli Medical College, Tirunelveli.

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PROTOCOL TITLE: A COMPARATIVE STUDY OF CHEMICAL SPHINCTEROTOMY (USING 2% DILTIAZEM) AND LATERAL INTERNAL SPHINCTEROTOMY FOR CHRONIC ANAL FISSURE.
PRINCIPAL INVESTIGATOR: Dr.DHEENADHAYALAN., MBBS.,
DESIGNATION OF PRINCIPAL INVESTIGATOR: PG STUDENT
DEPARTMENT & INSTITUTION: TIRUNELVELI MEDICAL COLLEGE, TIRUNELVELI

Dear, Dr.DHEENADHAYALAN., MBBS., The Tirunelveli Medical College Institutional Ethics Committee (TIREC) reviewed and discussed your application during the IEC meeting held on 10.03.2017

THE FOLLOWING DOCUMENTS WERE REVIEWED AND APPROVED

1.	TIREC Application Form	☐
2.	Study Protocol	☐
3.	Department Research Committee Approval	☐
4.	Patient Information Document and Consent Form in English and Vernacular Language	☐
5.	Investigator's Brochure	☐
6.	Proposed Methods for Patient Accrual Proposed	☐
7.	Curriculum Vitae of the Principal Investigator	☐
8.	Insurance /Compensation Policy	☐
9.	Investigator's Agreement with Sponsor	☐
10.	Investigator's Undertaking	☐
11.	DCGI/DGFT approval	☐
12.	Clinical Trial Agreement (CTA)	☐
13.	Memorandum of Understanding (MOU)/Material Transfer Agreement (MTA)	☐
14.	Clinical Trials Registry-India (CTRI) Registration	☐

THE PROTOCOL IS APPROVED IN ITS PRESENTED FORM ON THE FOLLOWING CONDITIONS

1. The approval is valid for a period of 2 year/s or duration of project whichever is later
2. The date of commencement of study should be informed
3. A written request should be submitted 3weeks before for renewal / extension of the validity
4. An annual status report should be submitted.
5. The TIREC will monitor the study
6. At the time of PI's retirement/leaving the institute, the study responsibility should be transferred to a person cleared by HOD
7. The PI should report to TIREC within 7 days of the occurrence of the SAE. If the SAE is Death, the Bioethics Cell should receive the SAE reporting form within 24 hours of the occurrence.
8. In the events of any protocol amendments, TIREC must be informed and the amendments should be highlighted in clear terms as follows:
   a) The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project. (Page no. Clause no. etc.)
   b) The PI must comment how proposed amendment will affect the ongoing trial. Alteration in the budgetary status, staff requirement should be clearly indicated and the revised budget form should be submitted.
   c) If the amendments require a change in the consent form, the copy of revised Consent Form should be submitted to Ethics Committee for approval. If the amendment demands a re-look at the toxicity or side effects to patients, the same should be documented.
   d) If there are any amendments in the trial design, these must be incorporated in the protocol, and other study documents. These revised documents should be submitted for approval of the IEC, only then can they be implemented.
   e) Approval for amendment changes must be obtained prior to implementation of changes.
   f) The amendment is unlikely to be approved by the IEC unless all the above information is provided.
   g) Any deviation/violation/waiver in the protocol must be informed.

STANDS APPROVED UNDER SEAL

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This is to certify that this dissertation work titled **"A COMPARATIVE STUDY OF CHEMICAL SPHINCTEROTOMY (USING 2% DILTIAZEM) AND LATERAL INTERNAL SPHINCTEROTOMY FOR CHRONIC ANAL FISSURE"** of the candidate **Dr.V. DHEENADHAYALAN** with registration Number **221611354** for the award of **M.S.** Degree in the branch of **GENERAL SURGERY.** I personally verified the urkund.com website for the purpose of plagiarism check. I found that the uploaded thesis file contains from introduction to conclusion pages and result shows **18 percentage** of plagiarism in the dissertation.

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CONTENTS

INTRODUCTION

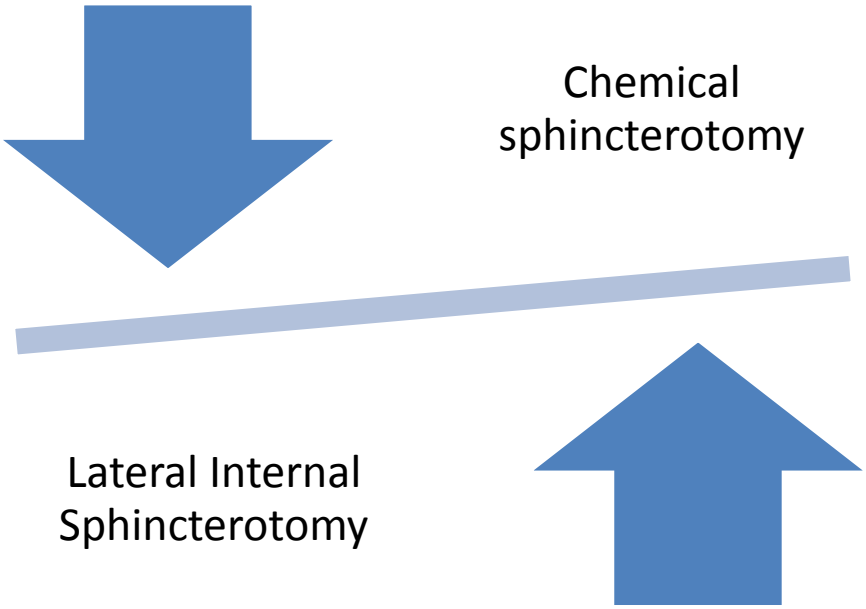
Anal Fissure is the most common painful condition of anal region, characterized by vertical ulcers affecting the distal end of the anal canal. It is more common that it affects 1 in 10 people and causes very disabling symptoms such as severe, excruciating perianal pain and anal bleeding making the patient to suffer both physically and mentally despite rest and adequate analgesics. Anal fissures behave more differently in the way that they are more persistent and relapsing than acute fissures which heal spontaneously.

Regarding the etiopathogenesis of Fissures, though the Persistent Hypertonia of the anal sphincter is claimed to be the well-established cause. Hence the available standard treatment options direct in relieving the spasm of the internal anal sphincter with medical methods and surgical methods. The gold standard treatment in the management for chronic anal fissure is Lateral Internal Sphincterotomy with healing rates above 95%. But the need for the alternative is always been there to overcome the surgical stress and risk of incontinence. There are various chemicals which carry out the same job of reducing the tone of internal sphincter through their pharmacodynamics and pharmacokinetic.

Properties, of which, Diltiazem, a calcium channel blocker with its distinct profile of excellent healing rates and mild side effects has been used in its topical form. Though many trials have already been done with 2 % Topical Diltiazem in management for chronic anal fissure, less significance has been paid to its

methodology, dosage and durability of usage which may be the reason for its higher recurrence rate.

This study has been designed by taking all the above into consideration and it compares the healing rates of chronic anal fissures using 2% Diltiazem as Chemical sphincterotomy with that of the Surgical Lateral Internal sphincterotomy (Surgical sphincterotomy) as the utmost objective. It also compares and analyze the other secondary objectives such as recovery of Pain, Bleeding per Rectum, risk of Incontinence and the recurrence in both procedures.



This clinical trial has been conducted in Tirunelveli Medical College Hospital, Tirunelveli with patients suffering from chronic Anal Fissure attending the Surgical Outpatient Department. Ethical committee approval was obtained in

well advance as per protocol. Present Study includes 190 patients of anal fissure treated over a period of 19 months (March 2017 to September 2018). Results has been detailed in both descriptive and statistical point of views and simplified in an understandable format for the viewers.

AIM OF THE STUDY

The utmost aim of the study is to compare the effectiveness of 2% Diltiazem (Topical Gel) with the Operative Lateral Internal Sphincterotomy in treating the chronic anal fissure, which correlates directly with the Healing rate of Fissure.

The secondary objectives are to compare the relief of other symptoms and florid aspects of the treatment, as mentioned below

A. Pain Relief

B. Bleeding per Anum

C. Recovery Time

D. Anal Incontinence

E. Florid aspects of Treatment.

F. Recurrence rate

G. Work resumption time

H. Rate of Conversion

MATERIALS AND METHODS

The study was conducted as a clinical trial at Tirunelveli Medical College Hospital, Tirunelveli during the period between March 2017 to September 2018

SAMPLE AND SAMPLE SIZE DEFINITIONS

Population:

All patients diagnosed to have chronic anal fissure attending the Surgery Out Patient Department (OPD) of Tirunelveli Medical College Hospital, Tirunelveli Diagnosis was based on Clinical history, examination and Proctoscopy.

Based on the patient's statement on excruciating pain while defecation and bleeding during defecation.

Clinical examination involves gentle separation of the buttocks and examination of the anus, to look for a vertical ulcer at anoderm in the distal end of the anal canal with or without a sentinel pile.

Inclusion criteria

Every patient between the age of 15 to 64 age presenting to the Surgical Outpatient department with complaints of painful passage of faeces and bleeding while passing tool for more than 6 weeks.

Exclusion Criteria

Patients with the following associated conditions were excluded from the study:

1. Inflammatory Bowel Disease
2. Tuberculosis
3. Hemorrhoids
4. Anal Malignancy
5. Anorectal Abscess
6. Immunocompromised patients
7. Previous history of fecal Incontinence and Anal Stenosis
8. Patient who have undergone previous anal surgeries
9. Patients with history of bleeding diathesis
10. Patients with cardiovascular diseases.

SAMPLE

From the above mentioned inclusion and exclusion criteria, samples for the study was undertaken.

SAMPLE SIZE

In this clinical trial-Parallel Study Design involves two groups, Sample size was calculated to be 150, having 75 in each group.

Formula:

$$N = Z^2 \{P1x (1-P1) + P2x (1-P2)\} / (P1-P2)^2$$

Z- Involves the Power and significance of alpha & beta errors Power was kept as 90% and p value significant at 0.05.

P1- Assumed success rate in Group A P2- Assumed success rate in Group B

From the observations of various studies, 80% efficacy was with Chemical Sphincterotomy (using 2% diltiazem) and 95% with Operative Lateral Internal Sphincterotomy. To calculate the difference between 95% confidence level & 80% power the minimum sample required is about 75 per group.

Based on the above calculation, sample size was calculated as 75 in each group with total of 150 patients. But the actual sample studied is 190 which is more than the needed volume.

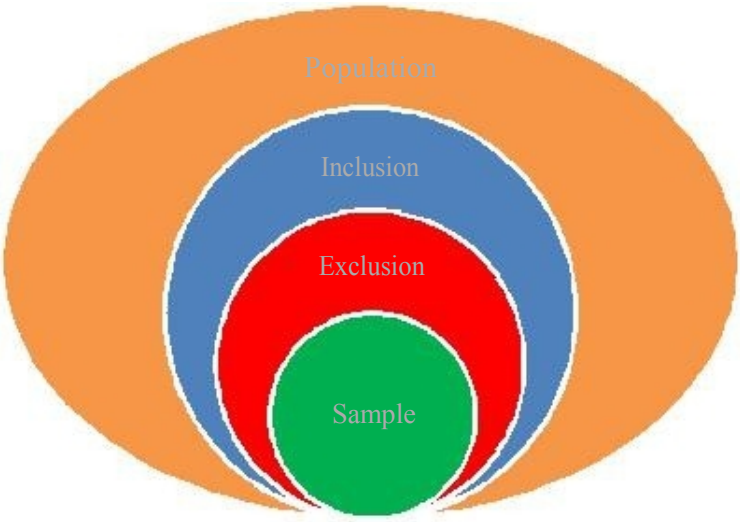


Fig. 3.1 Selection of Sample.

SAMPLING METHOD

Total 190 patients with Chronic Anal Fissure attending Surgical Out Patient Department were grouped in the study. Patients with Odd Numbers starting 1,3,5,7…189 were assigned to group A, who received treatment with 2% Topical Diltiazem as outpatients and the remaining even no of patients from 2,4, 6,.190 were categorized as group B (surgical lateral internal sphincterotomy). Patients belonging to Group B were admitted in the hospital for surgery.

METHODOLOGY[1-10]

- The Group A Patients were treated with a 2% Diltiazem gel (chemical sphincterotomy). The patients were taught individually to apply the gel (about a size of 1.5cm) to the anoderm twice daily for 6 consecutive weeks with well-maintained hygiene and technique.

- In the present Study the 2% Topical Diltiazem gel was used. Each tube weighed 30g and the dosage prescribed was 1.5cm for twice a day, measured in a small scale given with the gel. It was found that each 30g tube on milking came up to 124.5cm length. The daily maximum requirement per day was 1.5 x 2= 3cm, and that for 6weeks 42 days (6 weeks) was 42 x 3 = 126 cm. So on an average one tube was required for each patient to finish the course of the treatment. The cost of each tube was around 143 rupees, so the total cost of the treatment was 143 rupees
- The patients from B group were operated (lateral internal sphincterotomy) under spinal/general anaesthesia as inpatient in the hospital. In open method, incision was made over and across the intersphincteric groove and the sphincter muscles are divided after separating from the anal mucosa. The cost of this procedure could not be measured as in our hospital, the medical treatment is completely free of cost for them.
- Both the group of patients were asked to consume diet rich in fibres, analgesics and to undergo Sitz Bath and laxatives. the patients were

viewed in 2nd , 4th, 6th, 8th and 10th weekends during the course of treatment.

- At every visit, details regarding the fissure healing, pain relief and any adverse effect and the recurrence were noted.

- Also, enquiry was made regarding the flatus and faecal incontinence and was calculated based on Wexner's score.[Table3.1]

	Frequency				
Type of incontinence	Never	Rarely	Sometimes	Usually	Always
Solid	0	1	2	3	4
Liquid	0	1	2	3	4
Gas	0	1	2	3	4
Wears pad	0	1	2	3	4
Lifestyle alteration	0	1	2	3	4

Table 3.1 Wexner incontinence score

0 - Perfect continence; 1-7 - Good continence
8-14 Moderate incontinence 15-20 severe incontinence

- Healing of the fissure was assessed visually which was defined as the complete resolution of the fissure on examination

- Visual Analogue Score was used to analyse the intensity of pain.

- Every patient was supplied with a pain score chart [fig3.4]. They were asked to

circle the level of the pain in its daily. This score was graded from 0 to 10 and marked at one end-0 (no pain) and at the other end -10 (worst pain). 1-3 (mild pain), 4- 7 (moderate pain), 8-10 (severe pain). Our target was to achieve a pain score of less than 3, preferably near 0.

Fig. 3.4 Visual analogue Pain scoring chart

- Bleeding per Anus was also graded into the Following

  0 Nil bleeding
  1 Occasional blood spotting in stools (<1/week) [Minimal]
  2 Blood stained stools [Mild]
  3 Frank blood in stools [Moderate]
  4 Blood clots passing per rectum [Severe].

- Work resumption time was calculated in weeks which was defined as the time required by the patients to comply to daily routine work with symptomatic pain relief

- Recovery time was calculated in weeks which defined as the time taken for complete resolution of anal fissure.

- Anal Fissure was considered as recurrent if the fissure reappeared or causes symptomatic pain at the same site after 2 months of surgery or 6 weeks' therapy

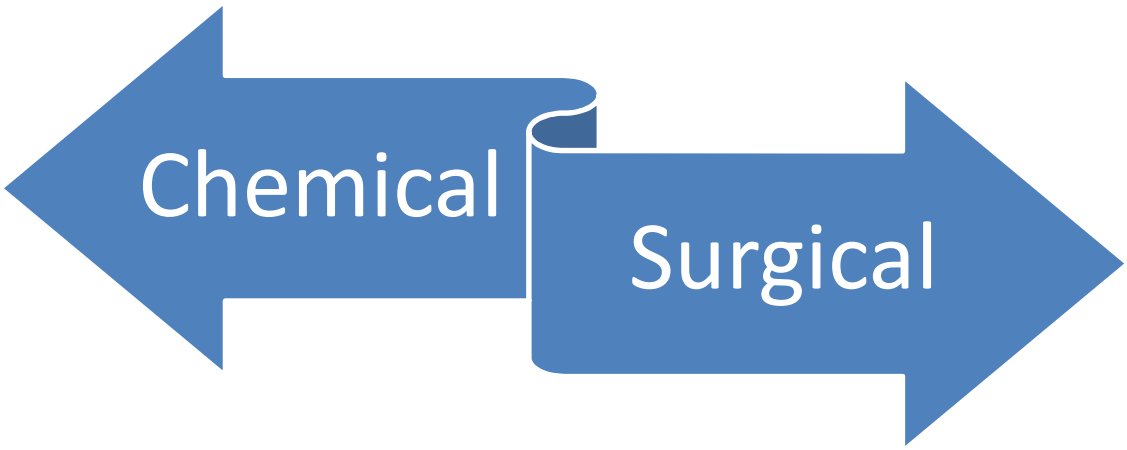
of 2% topical Diltiazem.

- Drop outs were those patients who quit the trial before completion of 10 weeks' trial.

- Patients belonging to Group A and who have completed 10 weeks of follow up and found refractory to treatment were switched over to operative method and followed up. But they were considered as Failure cases of Group A. Similarly, group B patient's refractory to operative treatment were switched over to Chemical sphincterotomy with patients consent. But the data stands distinct within Group A and B, but they were included in the Conversion Rate.

Screening Procedures :

The patients underwent clinical examination including visual & Per Rectal and Proctoscopic Examination, and were asked to fill up a questionnaire regarding follow up.



ANALYSIS

The following parameter were assessed

PRIMARY: Fissure Healing Rate

SECONDARY:

a. Recovery of Pain

b. Recovery of Bleeding per rectum

c. Recovery time

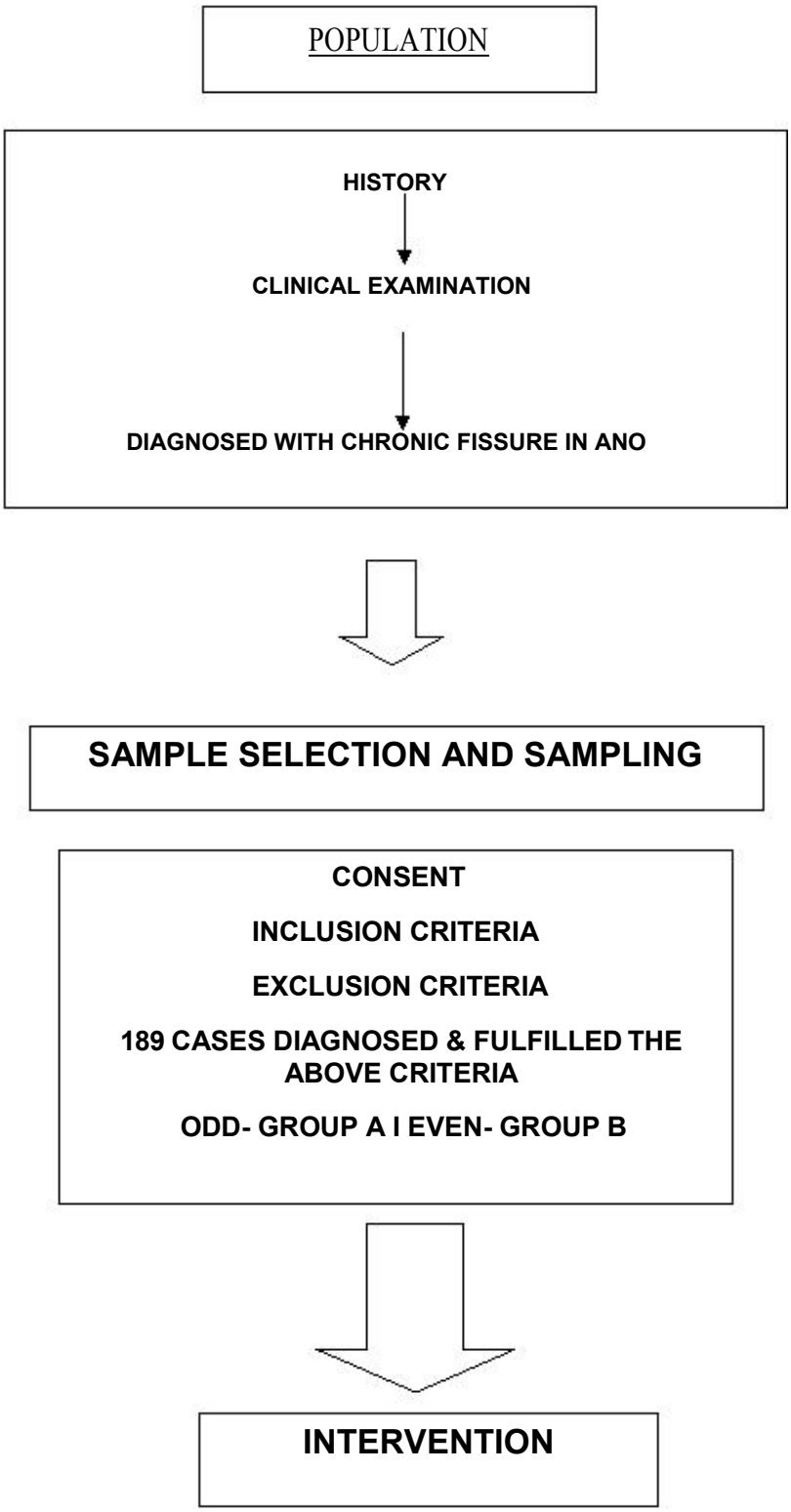
d. Risk of Anal Incontinence

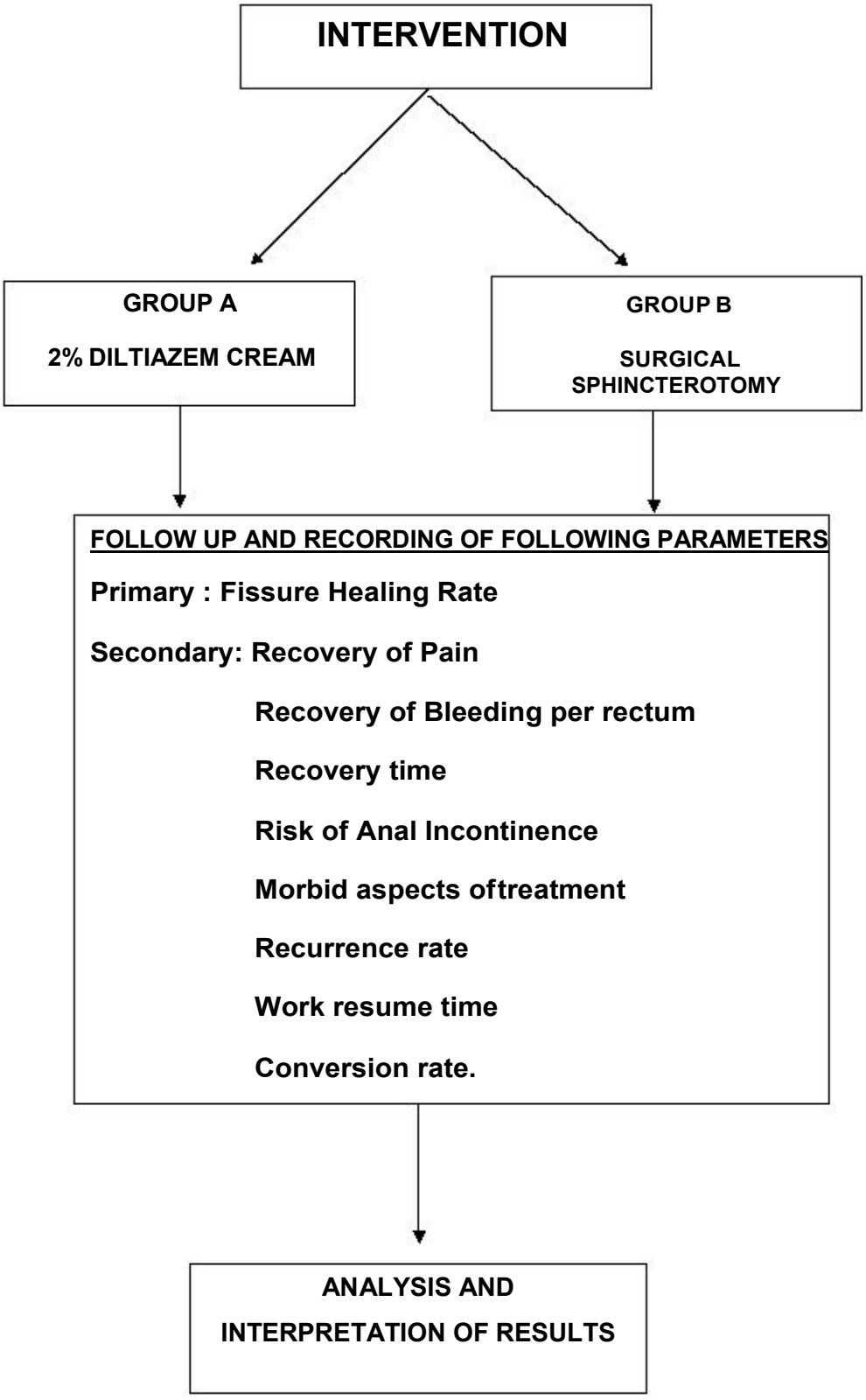
e. Morbid aspects of the treatment

f. Recurrence rate

g. Work resume time

h. Conversion rate.


POPULATION
HISTORY
CLINICAL EXAMINATION
DIAGNOSED WITH CHRONIC FISSURE IN ANO
SAMPLE SELECTION AND SAMPLING
CONSENT
INCLUSION CRITERIA
EXCLUSION CRITERIA
189 CASES DIAGNOSED & FULFILLED THE ABOVE CRITERIA
ODD- GROUP A I EVEN- GROUP B
INTERVENTION


INTERVENTION
GROUP A
2% DILTIAZEM CREAM
GROUP B
SURGICAL SPHINCTEROTOMY
FOLLOW UP AND RECORDING OF FOLLOWING PARAMETERS
Primary : Fissure Healing Rate
Secondary: Recovery of Pain
Recovery of Bleeding per rectum
Recovery time
Risk of Anal Incontinence
Morbid aspects oftreatment
Recurrence rate
Work resume time
Conversion rate.
ANALYSIS AND INTERPRETATION OF RESULTS

REVIEW OF LITERATURE

The principle clinical presentation of fissure in ano is intense anal pain during defecation, often associated with small amount of bright red bleeding noticed in toilet pan or toilet paper. There may be perianal swelling from the skin tag and discharge of mucus. There is often sensation of tearing during defecation and there may be a dull aching pain in the perineum 3 to 4 hours after bowel evacuation. Women are more commonly affected than men. In the ratio of approximately 58% to 42% respectively. Most patients are in the third decade of life, but fissure can occur at any age. Fissure may be exacerbated by recent episode of constipation and straining.

It commonly occurs in women after vaginal delivery. It may occur as a complication of severe diarrhea.

Inspection of anal region reveals a small shallow anal ulcer with a sentinel pile and edema usually in the posterior aspect of anal region particularly men. Out of women with fissure, 40% can occur anteriorly.

Surgical Anal Canal Anatomy

The anal canal commences at the level where the rectum passes through the pelvic diaphragm and ends at the anal verge.

Anorectal ring

The anorectal ring marks the junction between rectum and anal canal. It is formed by the joining of the puborectalis muscle, the deep external sphincter,

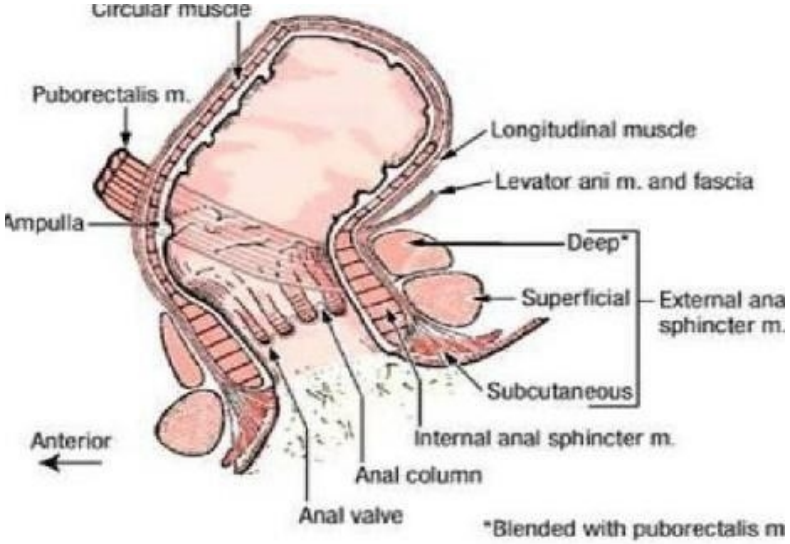
conjoint longitudinal muscle and the highest part of the internal sphincter

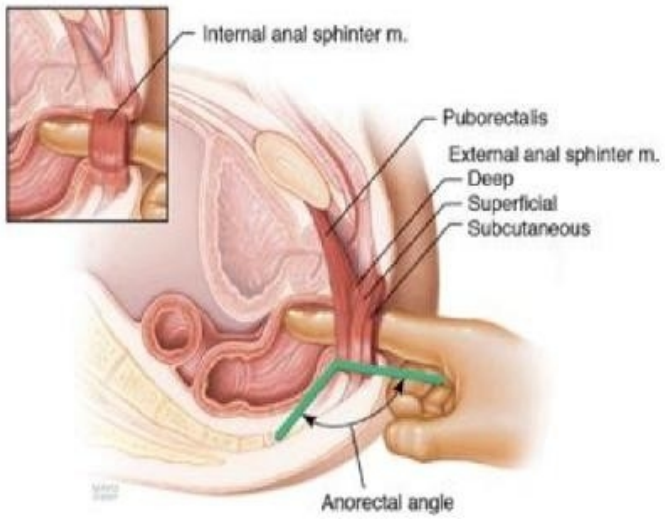
The puborectalis muscle

The puborectalis muscle is a part of the funnel shaped musclopelvic diaphragm. It maintains the angle between the anal canal and the rectum and ends the important parts of the continent mechanism.

The external sphincter

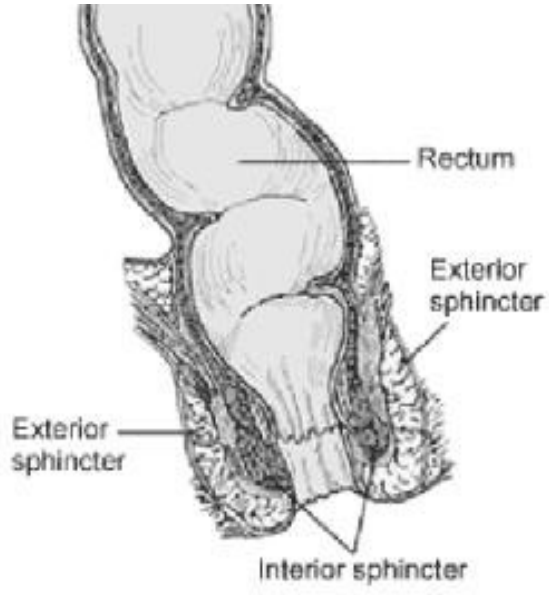
The external sphincter forms the bulk of the anal sphincter complex. Traditionally it has been subdivided into deep, superficial and subcutaneous portion. Being a somatic voluntary muscle, the external sphincter is red in colour and is innervated by pudental nerve.

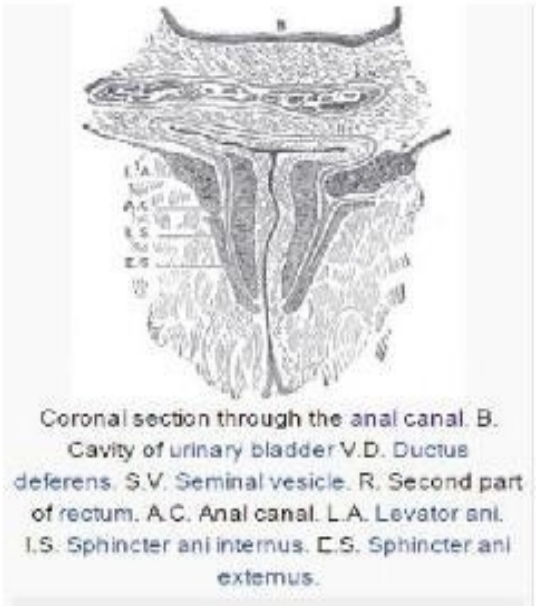




The intersphincteric plane

Between the externals sphincter laterally and the longitudinal muscle medially, exists a potential space – the intersphincteic plane this plane is important as it contains intersphincteric glands. The plane can be opened up surgically to access for operations on sphincter muscle.





Coronal section through the anal canal. B. Cavity of urinary bladder V.D. Ductus deferens. S.V. Seminal vesicle. R. Second part of rectum. A.C. Anal canal. L.A. Levator ani. I.S. Sphincter ani internus. E.S. Sphincter ani externus.

Internal sphincter

The internal sphincter is a thickened 2 -5 mm. it is a distal continuation of the circular muscle coat of the rectum which has a special property and which is a tonic state of contraction.

The epithelium and sub epithelial structure.

The pink columnar epithelium lining the rectum extends through the anorectal ring into the anal canal. Passing downwards into the mucus membrane becomes cuboidal and redder in colour whereas above the anal canal it is plum coloured. Just below the anal valve there is an abrupt albit waving transition to stratified squamous epithelium which is parchment colour. This wavy junction contributes the dentate line. The dentate line is most important landmark both morphologically and surgically representing he site of fusion of proctodeum and postallantoic gut and being the sites of crypts of Morgagni. The squamous

epithelium lining the lower anal canal is thin and shiny and is known as the anoderm. It differs from the true skin n that it has no epidermal appendages.

Blood supply

The blood supply of upper anal canal is constant with the bifurcation of the main trunk of superior rectal artery with right and left main branches and with subsequent division of the former into right and left branches determine the sites of hemorrhoids around the anal circumference. Superior rectal artery and inferior rectal artery

Venous drainage

The upper half of anal canal is drained by superior rectal vein, tributaries of inferior mesenteric vein. The middle rectal vein drain into internal iliac vein. The inferior rectal vein drains the lower part of anal canal and subcutaneous part of anal canal.

Anatomical distribution	Anal canal upper 2/3rd	Anal canal lower 1/3rd
Embryological Origin	Endoderm	Ectoderm
Blood supply	Superior Rectal artery (Portal)	Inferior Rectal artery (Systemic)
Lymphatics	Sacral & Internal Iliac nodes	Superficial Inguinal nodes
Nerve supply	Autonomic Plexus (Pain Insensitive)	Inferior rectal branch of Internal Pudendal Nerve(Pain Sensitive)
Epithelium	Columnar	Stratified Squamous
Haemorrhoids	Internal	External

Table. 4.1 Anal Canal anatomy

Embryology [41]

Hind gut opens into the posterior part of Cloaca forming the future upper part of Anal canal and the Ectoderm of Proctodeum (Anal Membrane) invaginates forming Anal pit, giving rise to lower part of Anal Canal. Subsequent degeneration of the Anal membrane establishes the continuity of the passage.

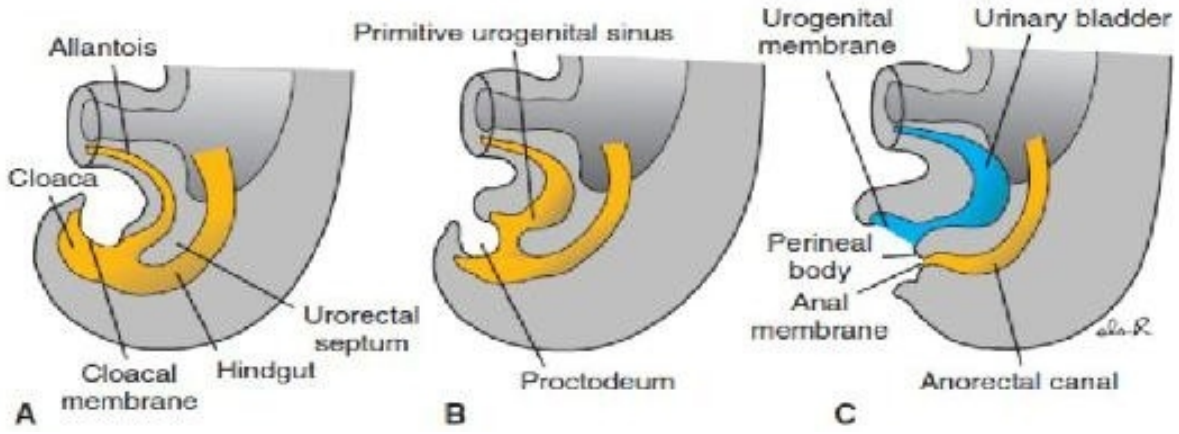


Fig. 4.3 Development of Anal Canal

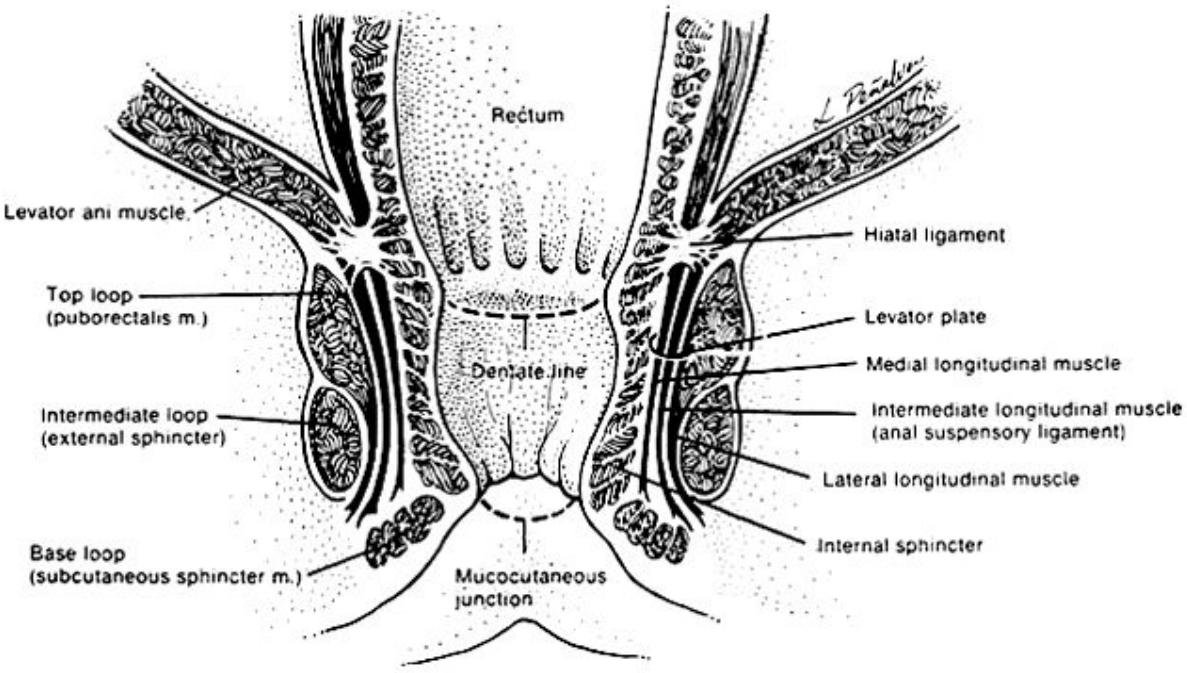


Fig 4.4 External Sphincter components

FISSURE IN ANO [10]

An anal fissure is a longitudinal split in the anoderm of the distal anal canal which extends form the anal verge proximally towards but not beyond dentate line

Classification

- ACUTE fissure in ano
- CHRONIC fissure in ano

ACUTE ANAL FISSURE

Acute anal fissure is defined as an occurrence of a longitudinal split or crack more commonly in the posterior aspect coupled with pain for a period of less than 6 weeks followed by spontaneous resolution thereafter.

CHRONIC FISSURE IN ANO

Chronic fissure is characterized by hypertrophic anal papilla internally and a sentinel pile externally (both consequent upto attempt and healing on breakdown). Fissure lasting more than 6 weeks.

A chronic fissure may have one or all of the following features

a) Due to the chronicity of the ulceration the internal sphincter fibres may be exposed at the base of the ulcer.

b) A Skin Tag may be seen at the distal margin of the Fissure, called as the

Sentinel pile.

c) At the proximal end there is the Hypertrophied Anal Papilla

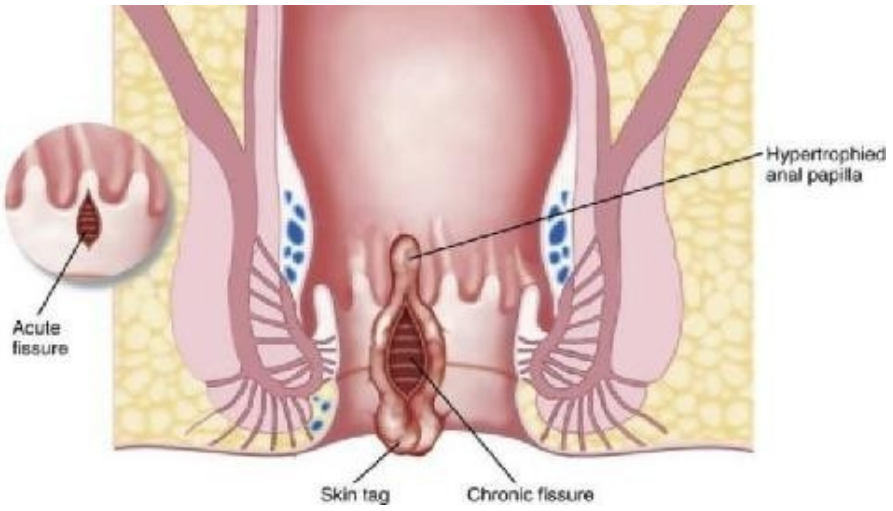


Fig 4.5 Acute and Chronic Anal Fissures

Symptoms

Severe anal pain associated with defecation followed by burning type of pain during bowel movement. Patients describe the pain as 'passage of broken Glasses. Bright red bleed per anus mostly as linear streaks.

Pathophysiology

The exact etiology of Anal fissure is yet to be established Conventionally it has been claimed that Mechanical trauma due to defecation is the cause of Fissure in ano, with constipation history forming only 20%

Internal Anal Sphincter Contraction has proved to be the main initiating factor in formation and propagation of the Fissures. Initially it was thought that

the internal sphincter contraction was the primary objective in causing fissure in secondary to mechanic trauma. This scenario keeps on continuing as the increased tone of the sphincters leads to further constipation and then further again causes local trauma during passage of stool, forming a vicious cycle. Internal sphincter hypertonia increases the resting pressure of anal canal above 90mm of Hg thereby distorting the blood flow of the anal canal as the mean pressure of the anal canal is around 85mm of Hg out of which the posterior midline is affected the most as it is supplied by end arteries and that these arteries penetrate through the internal sphincter before supplying the posterior midline. This reduction in posterior anodermal blood flow was documented by Doppler Flow study [13, 15]. It has also been found out that pain doesn't increase the sphincter spasm as demonstrated by the persistent Hypertonia of the sphincter muscles even upon applying the topical anesthesia [16]. Various theories and studies have been put in accord to the above.

One among the studies (Lund) established that the reduced Nitric Oxide synthesis is the reason for precipitating the Fissure by increasing the Sphincter Tone. Fissures are ischemic ulcers with the combination of raised resting tone of Internal anal sphincter and reduced Anodermal blood supply (Schouten et al study) at the Midline commonly. And of which the Posterior Midline is the most poorly perfused area of the anal canal accounting for about 90% of Anal Fissures. Anterior fissure accounts for less than 10% and 2% of them shall have both Anterior and Posterior Fissures. Fissures occurring off the midline must

raise thought on its etiology. They may arise due to Infective (Sexually transmitted infections, AIDS) or Inflammatory (Crohn's disease, Ulcerative Colitis) or malignancy.

Hence most modalities of management focus on relaxing the Internal anal sphincter spasm. This is because increased tone of Internal Anal sphincter remains the centre in vicious cycle of fissure propagation and perpetuation. Management ranges from topical ointments to surgical sphincterotomies. And the other modes used in the management are the stool softeners, Laxatives, sitz bath and topical analgesics which give symptomatic relief.

SURGICAL

Lord's Manual Dilatation

Lords anal dilatation was described during 1838[26] and was popularly used in the hemorrhoids surgery. The underlying principle was that under Anaesthesia mechanical pressure is applied to internal sphincter to stretch the fibres and release the spasm. Initially it was done using 8 fingers but now it is done gently with 4 finger technique [28]. Nielsen Et al using endoanal ultrasound showed that the dilatation leaded to irregular tears to both internal & external anal sphincters causing faecal incontinence with incontinence rate of 24.3% [32].

Fig 4.6 LORD'S ANAL DILATATION

Pneumatic Balloon Dilatation

To stabilize the procedure of anal dilatation, dilatation was done with the Parks retractor opening up to 4.8cm with a 40mm recto sigmoid balloon. As seen in Lords, here pneumatic Balloon pressure is used to stretch the sphincter with slightly lower incidence of faecal incontinence [29].

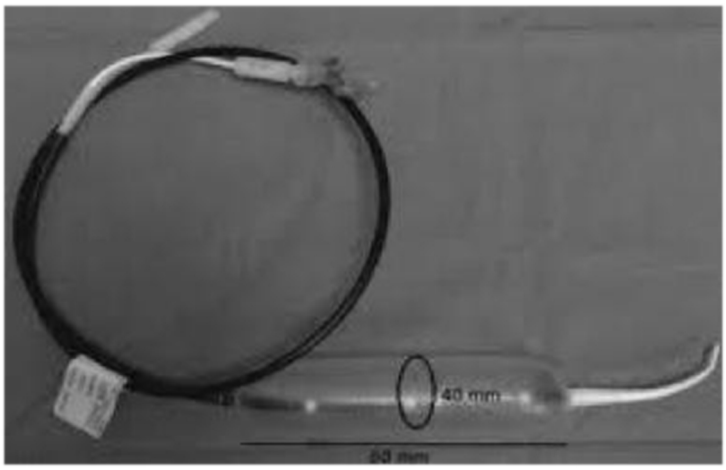


Fig 4.7 Pneumatic Rectal Dilator.

Fissurectomy

Surgical technique involves simple excision of the Fissure along with the skin tag. The resultant raw area can be left open or is closed with various options such as primary suturing, Y- V advancement flaps etc. Key hole deformity occurs if the raw area is left opened.

Anorectal Advancement Flap

Key hole deformity if occurred can be reduced by placing an Y-V Advanceent flap.

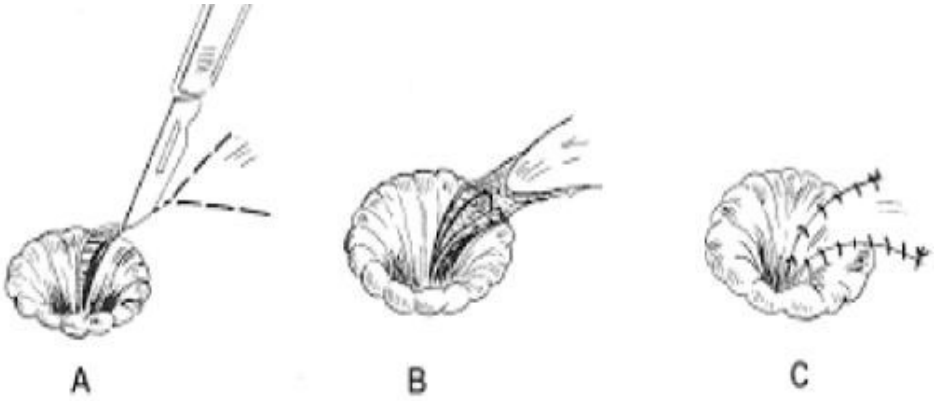


Fig 4.8 Y- V Advancement Flap Used In Fissure Healing

SPHINCTEROTOMY [17,18,19,20,24,25]

Posterior Sphincterotomy

Introduced by Eisenheimer in 1951, it involves the division of the Internal anal sphincter fibres at Posterior midline up to the Dentate line. It has now been replaced by the Lateral Sphincterotomy due to the adverse effects such as Keyhole defect and frequent Faecal soiling.

Lateral Sphincterotomy

It is the Gold standard in the treatment care of fissure in ano with over 96% cure rates. This method was re - published by Eisenheimer in 1951 and was modified by Notaras (1969). It involves division of the Internal sphincter along

the 3/9 ‘o’clock positions having better cure rates and reduced Incontinence (<10%). The two methods described are, the Open and Closed Methods. In Open method incision is made directly across the intersphincteric groove and the sphincter muscles are divided after separating from anal mucosa. Closed technique is a Subcutaneous technique starting with a small incision at the intersphincteric groove then inserting a scalpel with the blade parallel to the internal sphincter, advancing it along the intersphincteric groove and rotating towards the internal sphincter and dividing it.

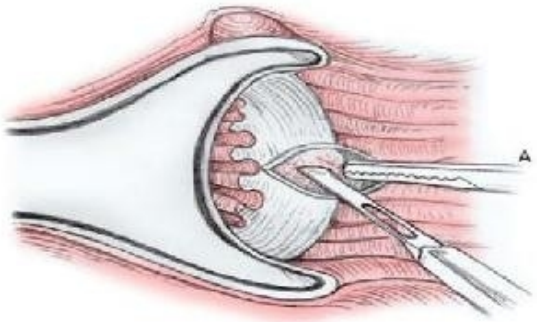


Fig 4.9 Open Lateral Sphincterotomy

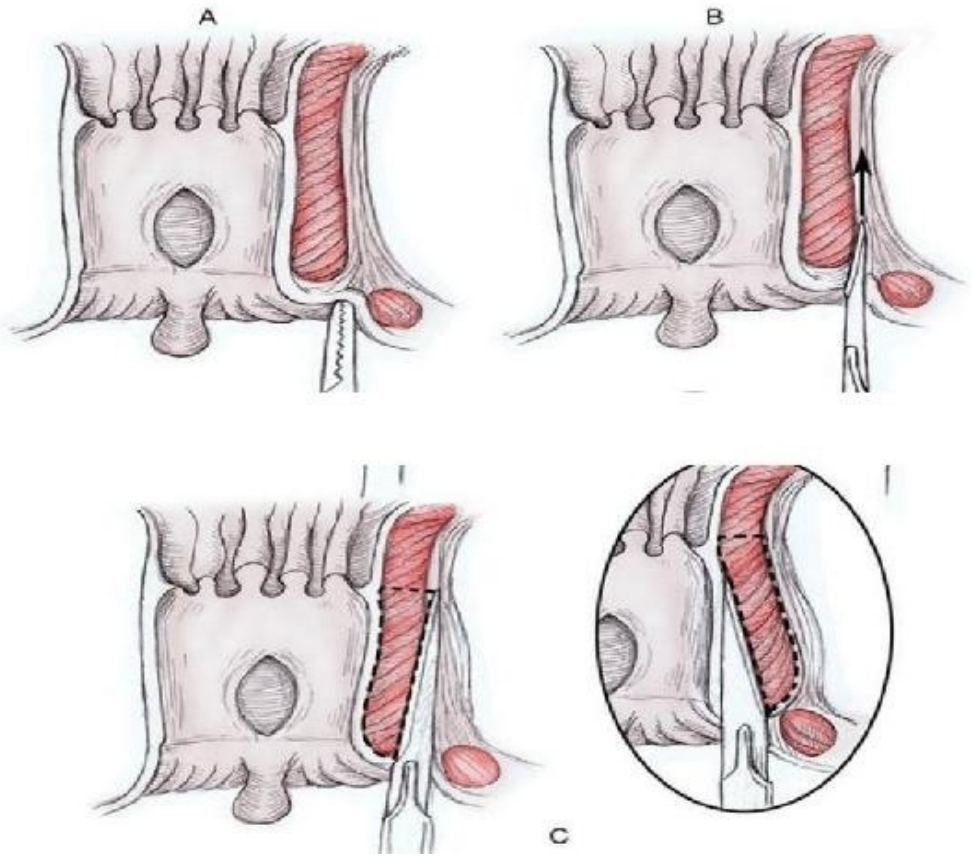


Fig 4.10 Closed Lateral Sphincterotomy in steps.

MEDICAL MANAGEMENT

Conservative management are usually used as the first line of therapy for Fissure in ano. It includes management ranging from High fibre diet, stool softeners, Warm sitz bath, topical Analgesics & Chemical Sphincterotomies. All are aimed at preventing constipation & hard stool movements, reducing the pain & the tone of the Internal Sphincter.

I. Chemical cauterization:

This is done by using silver nitrate or phenol-in-glycerine, which takes 4 to 8 weeks for healing of ulcer.

Drawbacks:

The toxicity of the drugs, accidental injection in the surrounding tissue amounts to general poisoning, hematoma and infection had refrain the surgeons from resorting to this method.

II. Chemical sphincterotomy using Nitric Oxide Donors:[38-40]

Nitric oxide is an important neurotransmitter of Non adrenergic – Non cholinergic nerve endings of gut mediating internal anal sphincter relaxation. It has been proved that chronic anal fissure is ischemic in origin due to poor blood supply and spasm of internal anal sphincter. Glyceryl trinitrate and other nitrates have a well-established role in healing of fissure by reducing the tone of internal

sphincter. A 2% GTN gel applied twice to the anoderm for 6 weeks have given a success rate of 68% on an average [43].

Drawbacks-

However, during the course of therapy, strict dietary restrictions to smoothen the stool are necessary. The major drawback is headache which amounts to 20 – 100% during the course of treatment. Despite have a good healing rate it has also got a recurrence rate.

III. Injection of Botulinum Toxin [52-59]

Botulinum toxins A, B, and E specifically cleave SNARE Proteins, preventing "neurosecretory vesicles" from docking/fusing with the interior surface of the plasma membrane of the nerve synapse, and so blocks the release of neurotransmitter. By inhibiting acetylcholine release, nerve impulses are blocked, causing the flaccid (sagging) paralysis of muscles. A 20 Units of type A botulinum toxin [Botox] is injected bilaterally (10 units each side) to the fissure. The toxin exerts its effects on the acetylcholine releasing presynaptic parasympathetic peripheral nerve endings as well as the ganglionic nerve endings, thereby leading to flaccid paralysis of the internal sphincter.

Fig 4.11 Botox Injection

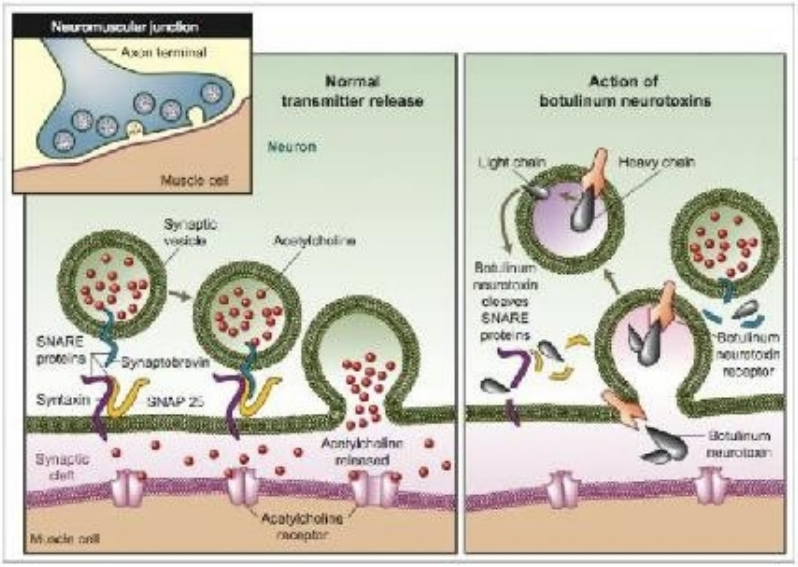


Fig4.12 Mechanism of Botulinium toxin

This causes sphincter paresis for about 3 months, which is sufficient for healing of a chronic non-complicated. It is well tolerated and can be administered on an outpatient basis. The healing rate reported is about 69-79%.

IV. Chemical sphincterotomy with Calcium Antagonists. [60-63]

Nifedipine belongs to L-type calcium channel antagonist. L-type Calcium channels are the principal Calcium channels in the GI smooth muscles. With the treatment of anal fissures, 20 mg of Nifedipine is given twice daily. Nifedipine is found effective in relieving the sphincter spasm there by allowing faster healing.

Drawback:

The major drawback of this management is reduced half-life and hence warranting frequent application of drugs and reduced sphincterolysis. Similarly, side effects like headache, palpitations, flushing, dizziness, colicky abdominal pain; ankle oedema, hyposmia and hypoguesia, nausea and diplopia have been reported

Chemical Sphincterotomy with Diltiazem:

Diltiazem is a NonDihydropyridines (Non-DHP), a Calcium channel blocker used in the treatment of hypertension, angina pectoris, and some types of arrhythmia (Type IV antiarrhythmic drug). It relaxes the smooth muscles in the walls of arteries, which dilates the arteries, allowing blood to flow more easily, and lowers blood pressure. Diltiazem is also being used in the treatment of anal fissures. Diltiazem can be taken orally or topically. When applied topically, it is made into a gel form using either vaseline or Phlojel. Phlojel absorbs the

diltiazem into the problem area better than the vaseline base. It has good short term success rates. When used topically, it is used as 2% gel over the anoderm. It decreases the tone of the Internal Anal sphincter and increases the blood supply of the region, thereby augmenting the Fissure healing. These results are comparable with Glyceryl trinitrate. These parameters have pushed to do many trials to establish the efficacy and tolerability in comparison to other modes of management.

Mechanism of Action	Calcium channel blocker • Relaxes the internal anal sphincter, reducing pain and increasing tissue blood
Preclinical Safety	Preclinical topical safety with 2% Diltiazem twice daily for 90 days
Clinical Pharmacology	Topical has <10% systemic exposure as oral dose but significantly greater effect on sphincter tone – i.e blood levels do not predict activity. Low exposure = better tolerability than oral diltiazem
Clinical Data	Ten clinical trials in 453 individuals. Similar or better reduction in pain, significantly better tolerability than GTN

Table. 4.2 Topical Diltiazem in Chemical Sphincterotomy.

Several trails have been carried out to compare the efficacy and morbidity of 2% topical Diltiazem in the management of chronic fissure in ano. Recent studies conclude that it could be used as a first line of medical management and surgery could be reserved for non-responders.

In Rithin Suvarna et al trial, 2012(JCDR/2012/4386:000) they compared the Diltiazem 2% topical ointment with that of the gold standard, Surgical Internal Sphincterotomy. It was a prospective trial with 100 patients in each group. The end result was that complete fissure healing was found better in surgical (95.87%) than the chemical group (69.23%). And also recurrence rate was 10.43% with Chemical Sphincterotomy but was nil with surgery. But chemical method had very little incidence of anal incontinence. This trial recommends the use of 2% Diltiazem as first line of treatment in chronic fissures. In Majid Aziz et al trial (Journal of Surgery Pakistan (International) 17 (1) January - March 2012) involving total of 60 patients with 30 in each group, showed that the healing rate of 2% diltiazem (33.33%) was very less compared to that of Lateral internal sphincterotomy(96.66%.) not favoring the use of chemical sphincterotomy.

In Giridhar C. M et al trial (J Clin Diagn Res. 2014 Oct; 8(10): NC01–NC02.) again compared the chemical with surgical sphincterotomy. The healing rates with 2% diltiazem was reported to better with 88.46% with mean healing time of 5.04 weeks. Concluding that the chemical sphincterotomy must be the first line of management of anal fissure.

In another study by Rithin Suvarna et al, 2%topical diltiazem was compared with that of 0.2% topical glyceryl trinitrate(GTN) in the management of chronic fissure in ano. Healing rate with topical Diltiazem (71.87%) was

better than GTN (68.23%) with p value of 0.0001, making it statistically significant. Also the major adverse effect was headache in both groups but with much lesser incidence in Diltiazem group (5.2% vs. 67%). Recurrence rate was also low in Diltiazem group (9.67% vs. 19.56%) suggesting that the chemical sphincterotomy was a better chemical agent with higher efficacy and lesser morbidity.

With the resources available, it can be concluded that chemical sphincterotomy must form the initial mode of management thereby reducing the hospital stay and avoiding the complications of surgery. Among the medical management, Chemical sphincterotomy using topical 2% Diltiazem has been considered to be the safest, simple, cost effective, efficacious method. Hence 2% topical Diltiazem can be used as the first line of management of chronic fissures leaving surgical sphincteromy reserved for only the non- responders.

STATISTICAL ANALYSIS

STUDY DEMOGRAPHY

The study involved 190 patients diagnosed with Chronic fissure in ano attending the Surgery OPD, Tirunelveli Medical College Hospital, Tirunelveli. Of which 7 were dropouts, who lost follow-up during the study period. Excluding the dropouts, the final sample was 183 patients with 90 in Group A and 93 in Group B.

AGE DISTRIBUTION

Age distribution of the Sample population ranged from 15 to 64 years, with an average age of 37 years.

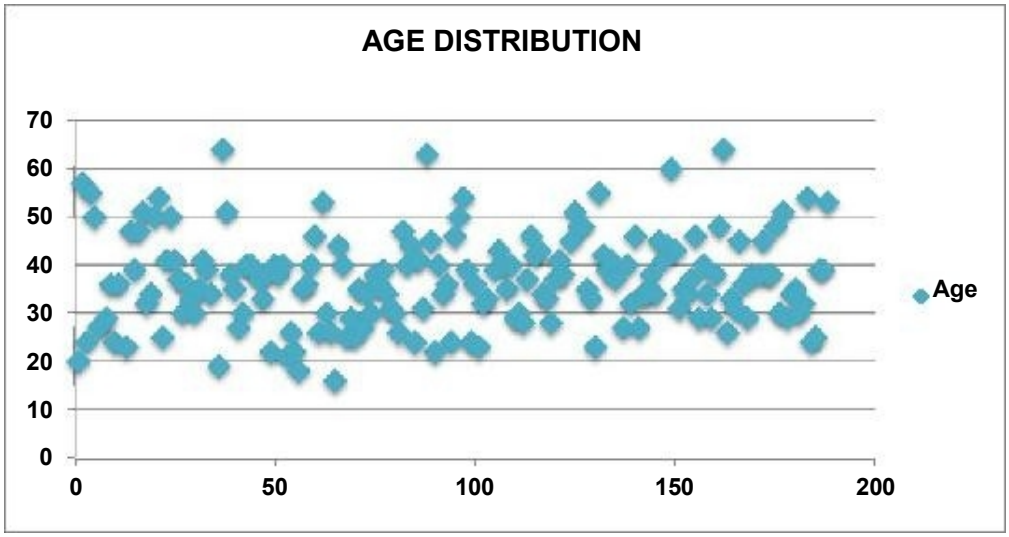


Figure 5.1 Age Distribution of The Sample

GENDER RATIO

Females outnumbered the male subjects with the ratio of 4:5 in the study which included 83 Males and 100 females.

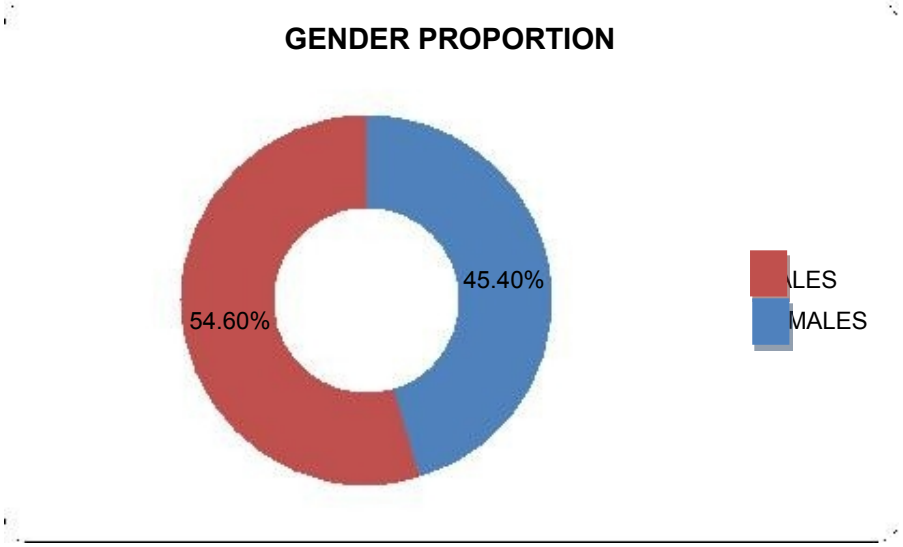


Figure 5.2 Gender Proportion CHRONIC FISSURE IN ANO

Patients presenting with chronic fissure in ano with bleeding per anum and pain were included in this study.

Chronic Anal fissure were further classified according to their site of location into

- ANTERIOR (7%)
- POSTERIOR (Most Common 91.25%)
- ANTERIOR + POSTERIOR (1.64%)

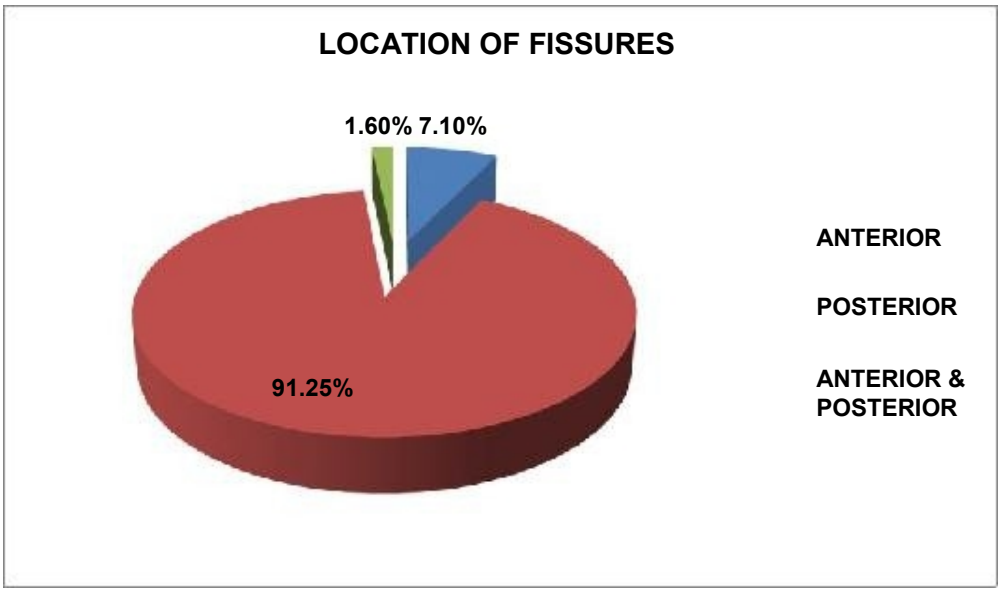


Figure 5.3 Locations of Chronic Anal Fissures.

ANALYSIS OF GROUP A – (Chemical Sphincterotomy)

In group A, 90 patients were treated with the Topical application of 2% Diltiazem gel twice daily for 6 consecutive weeks.

FISSURE HEALING

Healing of fissure in ano was complete only by the 4th week and the final cure rate was 84.4 %(76/90) at the 10th week.

FISSURE HEALING RATE					
2nd Wk	4th Wk	6th Wk	8th Wk	10th Wk	Final Cure Rate
0	38 (42.2%)	70 (77.78%)	76 (84.4%)	76 (84.4%)	76 (84.4%)

Table 5.1 Fissure Healing Rate in Chemical sphincterotomy.

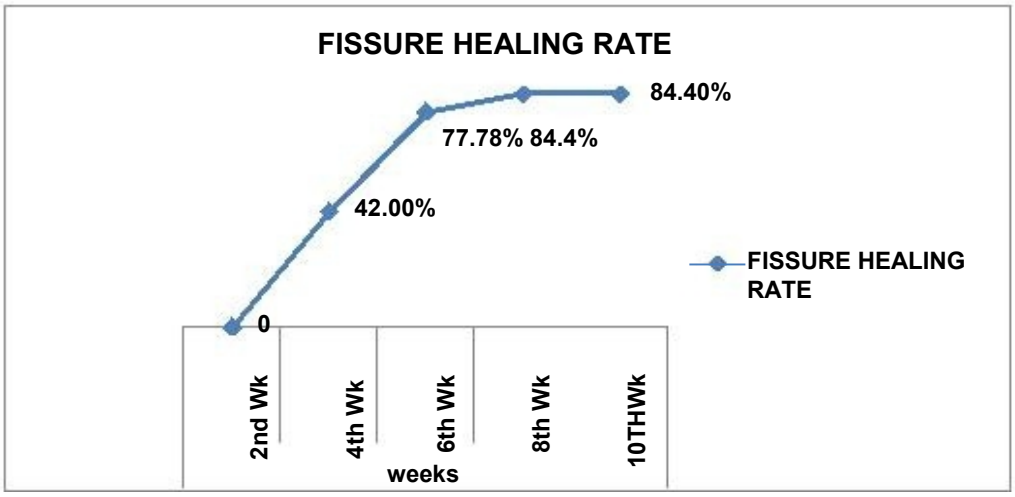


Figure 5.4 Fissure Healing Rate In Chemical Sphincterotomy.

AVERAGE RECOVERY TIME

The time taken for complete healing of fissure, on an average was about 5.18 Weeks in Group A.

PAIN RELIEF

The initial pain score was 7.66 in Group A and the response to treatment in the form of immediate pain relief was achieved early in the treatment, right from the 2nd week itself. Pain score dropped from 7.66 to 3.93 which occurred in first 2 weeks of treatment wherein the pain was nearly halved in first 2 weeks, allowing the patients to resume their work sooner. Pain score of 3 and lesser than 3 (Mild) was considered to be target and was achieved by 6th week.

INITIAL	2nd week	4th week	6th week	8th week	10thweek
7.66	3.93	3.41	2.81	2.36	2.24

Table 5.2 Average Pain Score In Group A

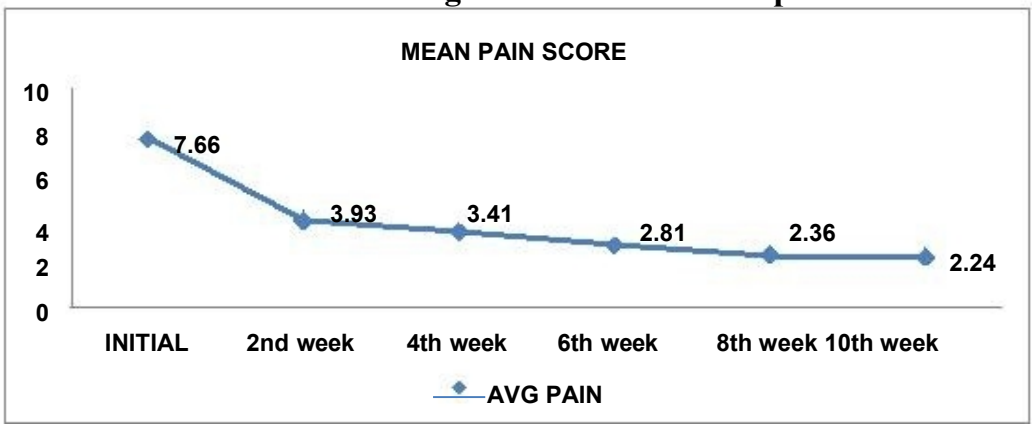


Figure 5.5 Mean Pain Score In Group A

RECOVERY OF BLEEDING PER ANUM

The most discomfort symptom of the patients - Bleeding per Anum was cured faster than the Pain Relief. About 75% of patients were freed of this discomforting symptom in first 2 weeks and by 10th week, 87.78% of patients were cured of this symptom.

BLEEDING PR RECOVERY				
2nd Wk	4thWk	6thWk	8thWk	10thWk
67 (74.4%)	79 (87.78%)	79 (87.78%)	79 (87.78%)	79 (87.78%)

Table 5.3 Recovery of Bleeding Per Rectum

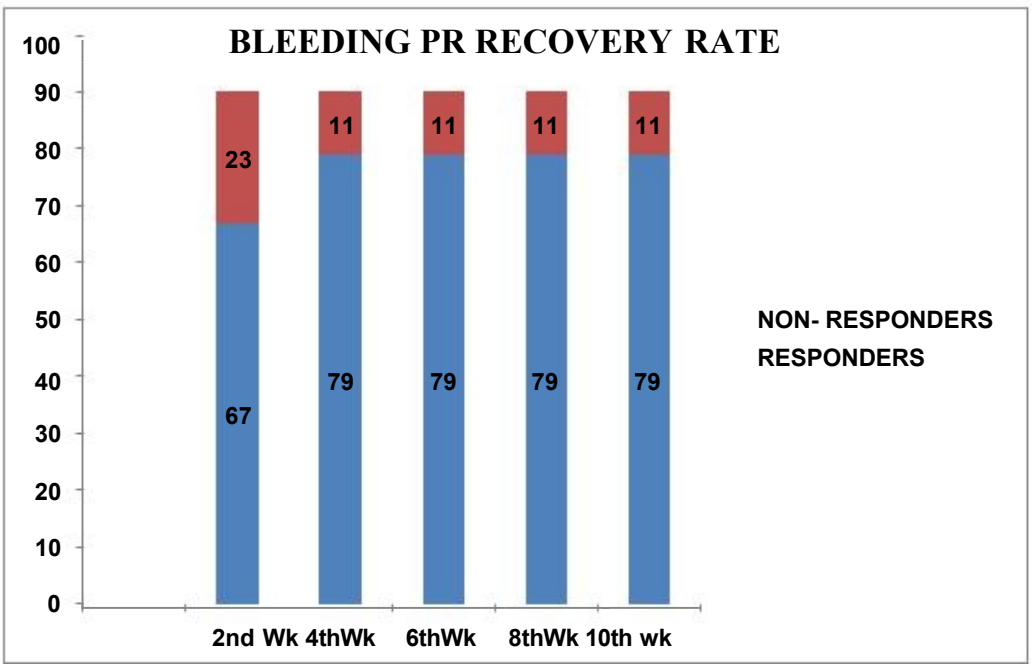


Figure 5.6 Bleeding Per Anum Recovery Rate

WORK RESUME TIME

Work resumuption time correlated directly with the relief of both Pain and Bleeding per anum which was about 3.37 Weeks in Group A. In other words, patients in group A resumed their day to day productive life in 3.37 weeks on an average.

MORBIDITY OF TREATMENT

Among the Group A involving the chemical Sphincterotomy using 2% Topical Diltiazem, the major adverse effects were Headache and Itching. The incidence of itching and headache were 15.6% and 6.7% respectively. The incidence of anal incontinence was very low which were only 2 out of 90 patients (2.22%) and was temporary

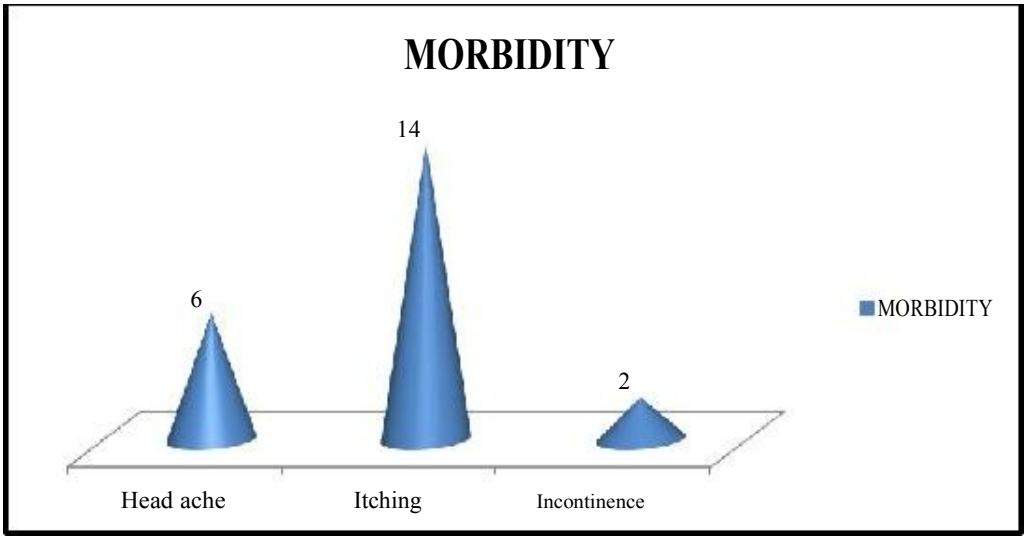


Figure 5.7 Morbidity of Chemical Sphincterotmy

RECURRENCE & CONVERSION RATE

The Recurrence rate in group A was 6.67% which was 6 patients developed Fissures at the same site after complete healing of the Fissure within 2 months past the treatment.

Patients who didn't respond to chemical methods and those who had recurrences shifted the standard surgical Sphincterotmy. There were 15 patients in this category leading to the conversion rate of 16.67%.

RECURRENCE RATE	CONVERSION RATE
6(6.67%)	15(16.67%)

Table 5.4 Recurrence & Conversion Rate

ANALYSIS OF GROUP B - (SURGICAL SPHINCTEROTOMY)

Group B patients (Surgical Sphincterotomy) were admitted as inpatient and were treated with the standard Surgical method of Lateral Internal Sphincterotomy under Spinal Anaesthesia. There were 93 patients in this group after excluding the dropouts.

FISSURE HEALING

Healing rates with the Gold Standard Surgical method was about 97.85%. Complete resolution of fissure was at 4th week.

FISSURE HEALING RATE-GROUP B				
2nd Wk	**4th Wk**	**6th Wk**	**8th Wk**	**10th Wk**
0	54 (58.06%)	88 (94.62%)	91 (97.85%)	91 (97.85%)

Table 5.5 Fissure Healing Rate in Group B

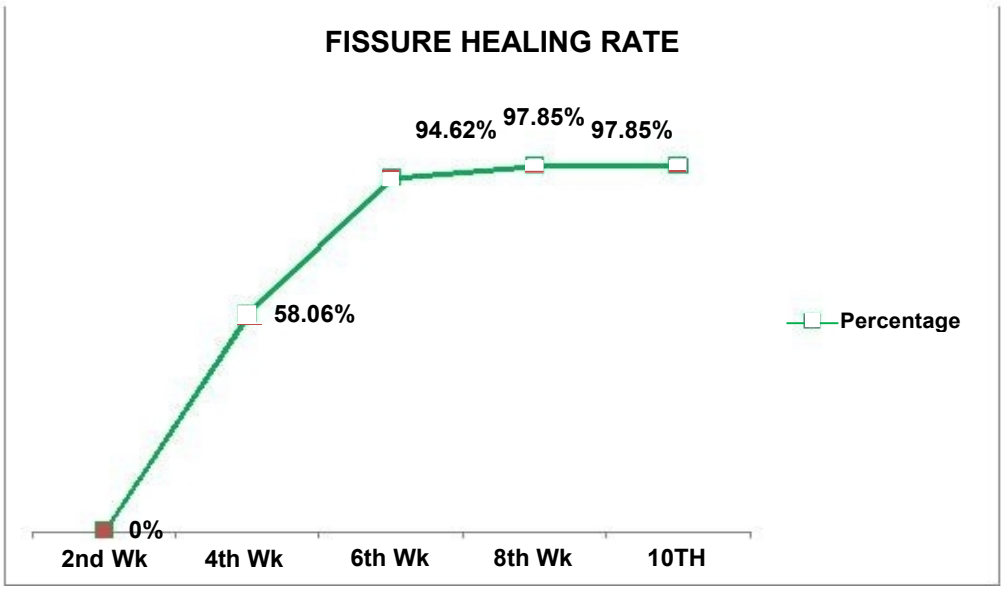


Figure 5.8 Fissure Healing Rates In Group B

AVERAGE RECOVERY TIME

The recovery time in Group B was 4.84 weeks during which the complete resolution of Fissure was achieved.

PAIN RELIEF

Pain relief was more pronounced starting from the 2nd week and the score less than 3 was achieved by 4th week itself. The final Pain score was 0.55 indicating complete pain relief in the patients.

AVERAGE PAIN SCORE					
Initial	**2nd week**	**4th week**	**6th week**	**8th week**	**10th week**
7.92	3.4	2.17	1.41	0.83	0.55

Table 5.6 Mean Pain Score in Group B

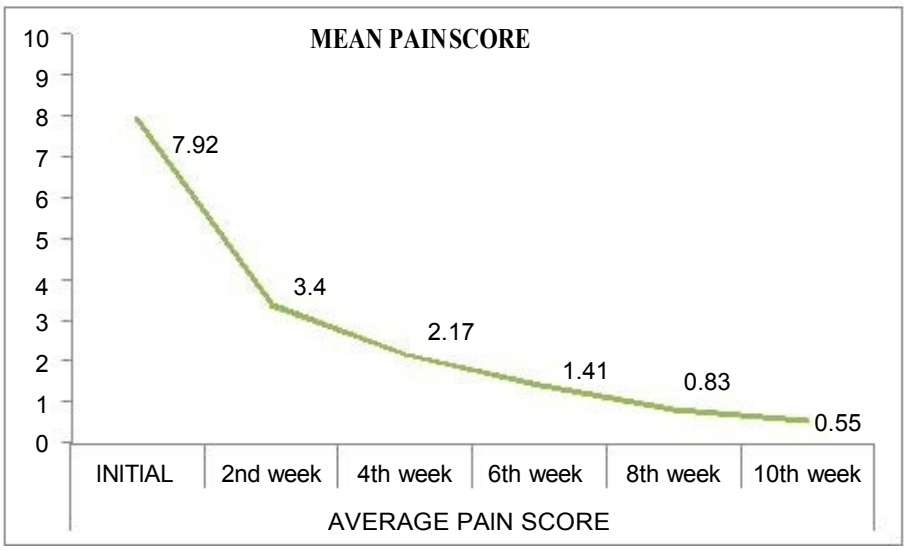


Figure 5.9 Pain Relief Rate in Group B

RECOVERY OF BLEEDING PER ANUM

Bleeding per anum was relieved in 68% of patients by second week and by 10th week, 98.92% of patients were relieved from bleeding per anum.

BLEEDING PR RECOVERY				
2nd Wk	**4thWk**	**6thWk**	**8thWk**	**10thWk**
63 (67.74%)	89 (95.7%)	92 (98.92%)	92 (98.92%)	92 (98.92%)

Table 5.7 Recovery of Bleeding Per Anum In Group B

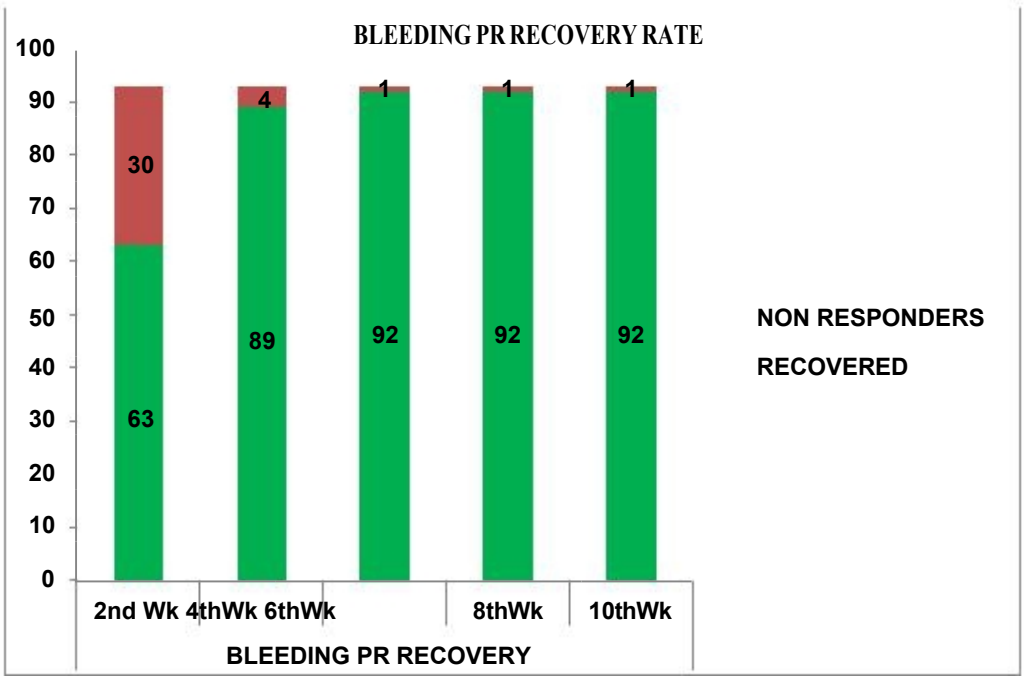


Figure 5.10 Recovery of Bleeding Per Anum In Group B

WORK RESUME TIME

Patients resumed their normal routine work by 3.19 weeks on an average in Group B after undergoing the operative procedure.

MORBIDITY OF TREATMENT

Immediate post-surgical complications included

- Post-operative Pain,
- Bleeding from Sphincterotomy site,
- surgical site Infection and Faecal Incontinence.

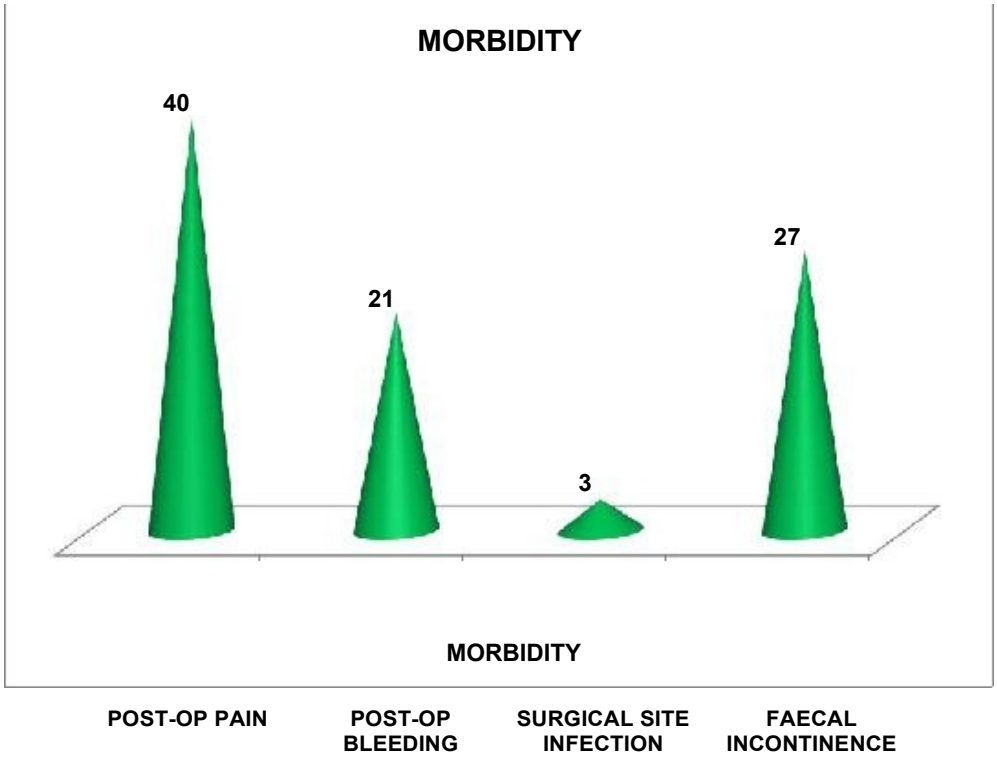


Figure 5.11 Morbidity of Surgical Sphincterotomy In Group B

MORBIDITY	PATIENTS	PERCENTAGE
Post-OP pain	40	43.01%
Post-OP bleeding	21	22.58%
Surgical Site Infection	3	3.23%
Faecal Incontinence	27	29.03%

Table 5.8 Morbidity of Surgical Sphincterotomy

Faecal Incontinence was the most devastating problem among the post-surgical patients, which was temporary in 88.89% cases and among the affected 27 patients, 24 had recovered from the problem in 10 weeks and 3 patients had permanent Faecal incontinence.

RECURRENCE AND CONVERSION RATE

In Group B involving the Surgical sphincterotomy method there was nil recurrence and the conversion rate was 2.15% (2 out of 93), proving the reliability of this Gold Standard method.

RECURRENCE RATE	CONVERSION RATE
0	2(2.15%)

Table 5.9 Recurrences and Conversion In Group B

STATISTICAL COMPARISON OF BOTH GROUP A & B

Statistical analysis

In the study, the statistical methods were, for quantitative data, descriptive statistics was presented by Normal, Mean, Standard Deviation and Range. For qualitative data, frequency count N and percentage were displayed in a tabular manner.

To analyze the data, an appropriate statistical tests were applied which compares the two groups Independent Samples Test- t test for Equality of Means by using statistical software SPSS (version 16.0) and Other data displayed by various tables and charts by using Microsoft excel (windows 2010).

*Significant at $p < 0.05$

** very significant $p < 0.01$

*** highly significant $p < 0.001$, *** highly significant $p < 0.000$

Independent Samples Test							
	t-test for Equality of Means					95% C I of the Difference	
PARAMETERS	**Mean Difference**	**t**	**df**	**p value**	**Std. Error Difference**	**Lower**	**Upper**
INITIAL PAIN	-0.18	-1.441	181	0.151	0.125	-0.427	0.067
PAIN SCORE 2ndweek	0.546	2.42	181	0.016*	0.226	0.101	0.992
PAIN SCORE 4thweek	1.239	5.494	181	0.0001***	0.226	0.794	1.684
PAIN SCORE 6thweek	1.413	5.694	181	0.0001***	0.248	0.923	1.903
PAIN SCORE 8thweek	1.528	6.44	181	0.0001***	0.237	1.06	1.996
PAIN SCORE 10thweek	1.739	7.12	181	0.0001***	0.244	1.257	2.221
BPR2ndWk	-0.067	-0.997	181	0.32	0.067	-0.2	0.066
BPR4thWk	0.079	1.963	181	0.051*	0.04	0	0.159
BPR6thWk	0.134	3.03	181	0.003**	0.044	0.047	0.221
BPR8thWk	0.123	3.048	181	0.003**	0.04	0.043	0.202
BPR10thWk	0.123	3.048	181	0.003**	0.04	0.043	0.202
FH4thWk	-0.158	-2.158	181	0.032*	0.073	-0.303	-0.014
FH6thWk	-0.168	-3.403	181	0.001**	0.05	-0.266	-0.071
FH8thWk	-0.134	-3.286	181	0.001**	0.041	-0.215	-0.054
FINAL CURE RATE	-0.123	-3.093	181	0.002**	0.04	-0.201	-0.045
INCONTINENCE	-0.268	-5.308	181	0.0001***	0.051	-0.368	-0.168
INC –TEMP	-0.236	-4.827	181	0.0001***	0.049	-0.332	-0.139
INC-PERMANENT	-0.033	-1.732	180	0.085	0.019	-0.07	0.005
Work Resume time	0.182	0.749	165	0.455	0.242	-0.297	0.66
RECOVERYTIME	0.391	2.06	166	0.041*	0.19	0.016	0.765
RECURRENCE	0.056	1.982	181	0.049*	0.028	0	0.112
CONVERSION	0.16	3.896	178	0.0001***	0.041	0.079	0.24

Table 5.10 Statistical Analysis of the Study

{Df- degree of freedom. BPR- Bleeding per rectum, FH- Fissure healing, INC- Incontinence.}

FISSURE HEALING RATES OF GROUP A & B

The overall healing rates were more pronounced in Group B with 97.85% of cure rates when compared to the Group A (84.4%). Also response was quicker in Group B starting from 4th week.

FISSURE HEALINGRATE						
Group	**2nd week**	**4th week**	**6th week**	**8th week**	**10th week**	**Success Rate**
A	0	38 (42.2%)	70 (77.78%)	76 (84.4%)	76 (84.4%)	76(84.4%)
B	0	54 (58.06%)	88 (94.62%)	91 (97.85%)	91 (97.85%)	91 (97.85%)

Table 5.11 Comparison of Fissure Healing Rates In Group A& B

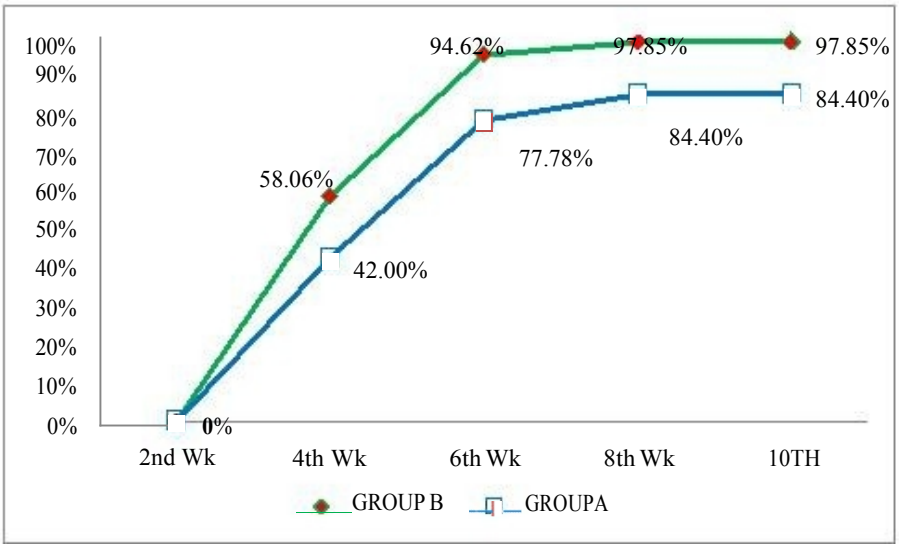


Figure 5.12 Comparison of Healing Rates In Group A & B

The p value was found to be significantly right from the 4th week (0.032*) and the final cure rate was statistically more consistent with a p value of 0.002**. Group B patients who underwent Surgical sphincterotomy had a better cure rate than the Group A patients with Chemical Sphincterotomy.

Independent Samples Test							
	t-test for Equality of Means					95% C I of the Difference	
Fissure Healing over Weeks	**Mean Difference**	**t**	**df**	**p value**	**Std. Error Difference**	**Lower**	**Upper**
4thWeek	-0.158	-2.158	181	0.032*	0.073	-0.303	-0.014
6thWeek	-0.168	-3.403	181	0.001**	0.05	-0.266	-0.071
8thWeek	-0.134	-3.286	181	0.001**	0.041	-0.215	-0.054
Final Cure Rate 10th week	-0.123	-3.093	181	0.002**	0.04	-0.201	-0.045

Table 5.12 Fissure Healing Rates- p Values

AVERAGE RECOVERY TIME

The average recovery time was shorter in Group B (4.84 Weeks) than in Group A (5.18 Weeks). The p value 0.041* was statistically significant.

Independent Samples Test							
	t-test for Equality of Means					95% C I of the Difference	
	Mean Difference	T	df	p value	Std. Error Difference	Lower	Upper
RECOVERY TIME	0.391	2.06	166	0.041	0.19	0.016	0.765

Table 5.13 Recovery Time Comparison

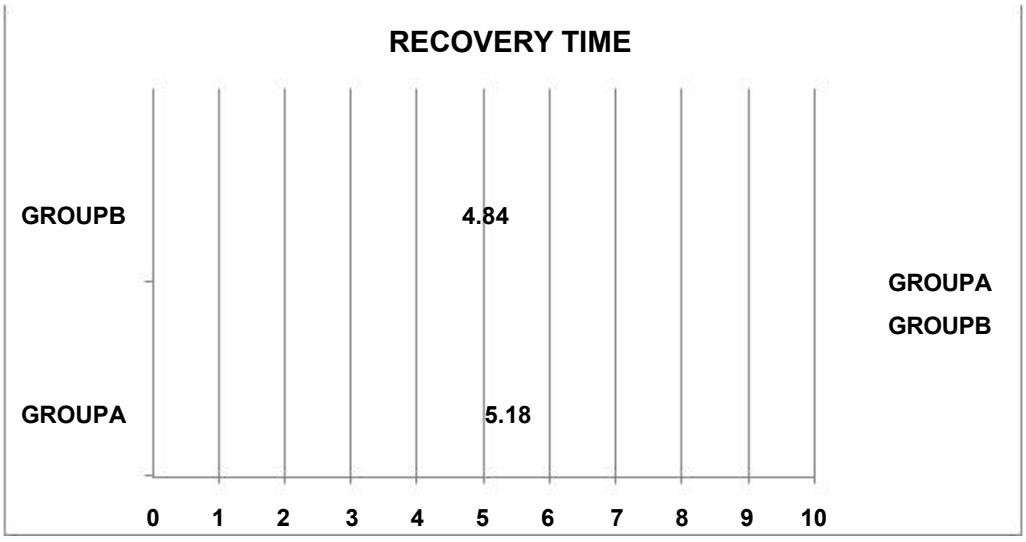


Figure 5.13 Comparison of Average Recovery Time

PAIN RELIEF

On comparison the Pain relief was much better and quicker in Group B compared to Group A. at the end of 4th week, the pain scale dropped below 3, whereas it was only in the 6th week with Group A. The final pain scores were 0.55 in Group B and 2.24 in Group A concluding that the pain relief was better in group B

PAIN SCORE MEAN						
Group	**Initial**	**2nd week**	**4th week**	**6th week**	**8th week**	**10th week**
A	7.66	3.93	3.41	2.81	2.36	2.24
B	7.92	3.4	2.17	1.41	0.83	0.55

Table 5.14 Mean Pain Score In Group A & B

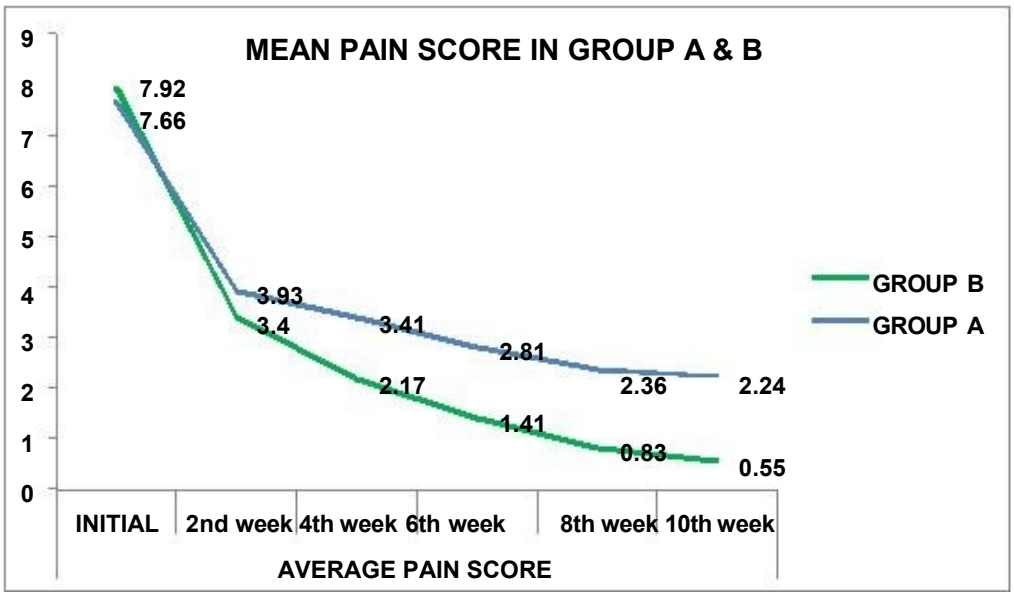


Figure 5.14 Comparisons Of Pain Scores In Group A And B

From Statistical point of view, the Pain relief was significant from the 2nd week itself (p=0.016*) and then onwards it was very much significant (p=0.0001***), clearly depicting that the Pain Relief in Group B was certainly better than Group A.

Independent Samples Test							
	t-test for Equality of Means					95% Confidence Interval	
Pain Score	**Mean Difference**	**t**	**df**	**p value**	**Std. Error Difference**	**Lower**	**Upper**
Initial Pain	-0.18	-1.441	181	0.151	0.125	-0.427	0.067
2ndweek	0.546	2.42	181	0.016*	0.226	0.101	0.992
4thweek	1.239	5.494	181	0.0001***	0.226	0.794	1.684
6thweek	1.413	5.694	181	0.0001***	0.248	0.923	1.903
8thweek	1.528	6.44	181	0.0001***	0.237	1.06	1.996

Table 5.15 Statistical p Value for Pain Relief RECOVERY OF BLEEDING PER ANUM

At the end of 10th week, Bleeding per anum became nil for 87.78% of patients in Group A and 98.92% of patients in Group B, which correlated with the Fissure healing rates. Recovery was actually better in Group B but appeared to be little faster in Group A during the early course of treatment which is first 2 weeks

	BLEEDING PR RECOVERY				
Group	**2nd Wk**	**4thWk**	**6thWk**	**8thWk**	**10thWk**
A	67 (74.4%)	79 (87.78%)	79 (87.78%)	79 (87.78%)	79 (87.78%)
B	63 (67.74%)	89 (95.7%)	92 (98.92%)	92 (98.92%)	92 (98.92%)

Table 5.16 Comparison Of Recovery Of Bleeding Per Anum

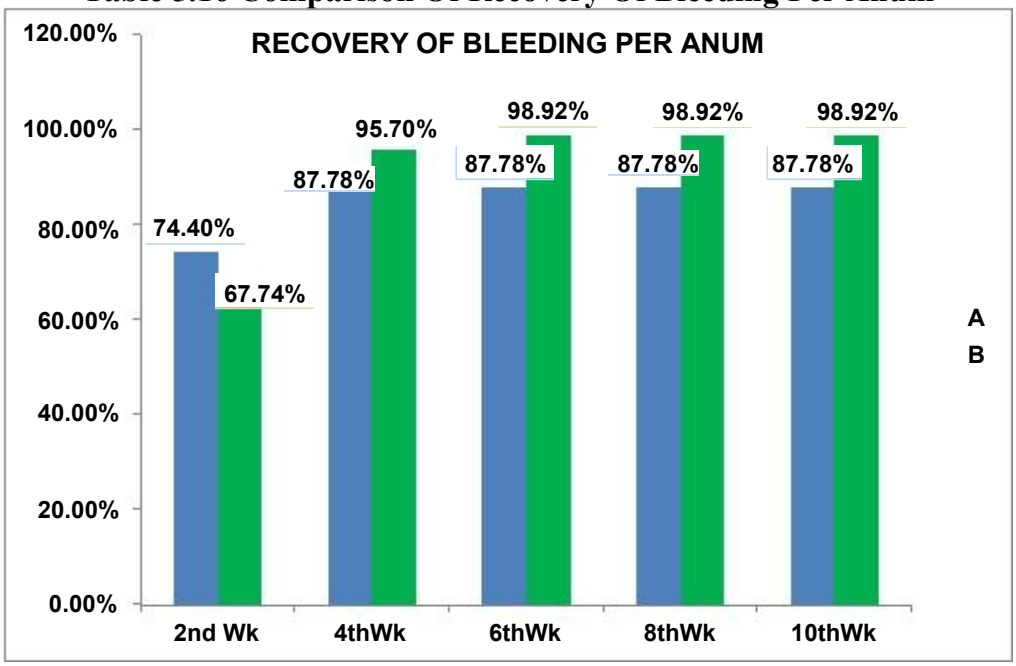


Figure 5.15 Comparison of Recovery Of Bleeding Per Anum In Group A & B

The recovery of Bleeding per anum was statistically significant from the 4th week onwards with p value of 0.051*. In the subsequent weeks (6th,8th & 10thweek) the p value was very significant (p=0.003**), showing that the recovery was better in Group B.

Independent Samples Test							
	t-test for Equality of Means					95% Confidence Interval	
Pain Score	Mean Difference	t	df	p value	Std. Error Difference	Lower	Upper
2ndWk	-0.067	-0.997	181	0.32	0.067	-0.2	0.066
4thWk	0.079	1.963	181	0.051*	0.04	0	0.159
6thWk	0.134	3.03	181	0.003**	0.044	0.047	0.221
8thWk	0.123	3.048	181	0.003**	0.04	0.043	0.202
10thWk	0.123	3.048	181	0.003**	0.04	0.043	0.202

Table 5.17 Comparison Of Recovery Of Bleeding Per Anum In Group A & B

WORK RESUME TIME

Work resuming Time was better with Group B (3.19Weeks) over Group A (3.37 Weeks) with p value of 0.455, giving not much of statistical significance.

MORBIDITY OF TREATMENT

Each group had its own specific morbid aspects such as Headache & Itching in Group A and Post-operative pain, Surgical site bleeding & Infection in Group B, which could not be compared.

Faecal incontinence was the factor specially measured in both groups. Group A patients had better continence profile than the Group B

FAECAL INCONTINENCE			
GROUP	**+/-**	**TEMP**	**PERMANENT**
A	2(2.22%)	2	0
B	27(29.03%)	24(25.80%)	3(3.22%)

Table 5.18 Comparison Of Faecal Incontinence

And that p value was very much significant (0.0001***), suggesting that the incidence of Faecal incontinence in Group A was very rare, while it was common with (Group B) Post-surgical patients.

Independent Samples Test							
	t-test for Equality of Means					95% Confidence Interval	
	Mean Difference	**t**	**df**	**p value**	**Std. Error Difference**	**Lower**	**Upper**
Incontinence	-0.268	-5.308	181	0.0001***	0.051	-0.368	-0.168

Table 5.19 Faecal Incontinence Comparison p Value.

RECURRENCE AND CONVERSION RATE

Surgical management provided nil recurrence and its conversion rate due to failure was only 2.15% (2/93). While in Group A, the Recurrence was 6 out of 90(6.67%) and the conversion rate was 16.67% (15 out of 90, including both failures and recurrence cases). Statistical analysis showed that the Recurrence in Group A was significant (p=0.049*) and the conversion rate was very much significant (p=0.0001***).

Independent Samples Test							
	t-test for Equality of Means					% Confidence Interval	
	Mean Difference	t	D f	p value	Std. Error	Lower limit	Upper limit
Recurrence rate	0.056	1.982	181	0.049*	0.028	0	0.112
Conversion rate	0.16	3.896	178	0.0001***	0.041	0.079	0.24

Table 5.20 Statistical p Values of Recurrence & Conversion Rates.

DISCUSSION

The analysis of the study between both the two groups were done and the results were justified with literature for establishing its significance. Starting from the primary objective of Fissure healing rates to the secondary objectives of recovery of Pain, Bleeding Per anum, Morbidity of the treatment & Recurrence rate were analyzed and discussed in a detailed manner.

Fissure Healing Rate [71-76]

In the present study the overall healing rates were better in Group B with 97.85% of cure rates when compared to that of the Group A (84.4%). In our study, fissure completely resolved by 4 to 8 weeks in both the groups. But response was quicker in Group B starting from 4^{th} week.

When compared with the previous similar studies in the literature the healing rate of chemical method with 2% Topical Diltiazem were ranging from 60 to 89%. The Fissure healing rate in the present study is comparable with most of the studies.

Study	Healing rate with Diltiazem 2%
Rithin Suvarna Et al 2012	69.23%
Giridhar C. M Et al 2014	88.4%
Ansar Latif Et al 2013	74%
Manjunath S Kotennava Et al 2012	60%
Rajan vaithyanathan Et al 2015	71%
Madhusudhan M. Et 2014	89.36%
Nelson et al. 2012	80%
Sanei et al. 2009	67%
Present study	**84.4%**

Table 6.1 Healing Rates with 2 % Diltiazem in Chronic Fissure in Ano.

The healing rates with Surgical method was constantly high (>95%) in all the above trials including the present study.

Recovery time [71-76]

The average Recovery time with Topical Diltiazem was 5.18 weeks which is one of the lesser recovery time as compared to literature(Table6.2) and is very close to that of the Surgical method(4.84 weeks in the present study).

Study	Average recovery time with topical 2%diltiazem
Sanei et al. 2009	7.58±2.01
Abd Elhady et al. 2009	5.1±1.13 weeks
Manjunath S Kotennavar et al 2012	7.2 weeks
Giridhar C. M et al 2014	5.04 weeks
PRESENT STUDY	**5.18 weeks**

Table 6.2 Average Recovery Time with 2% Topical Diltiazem

Pain Recovery [71-76]

On comparison, the Pain relief was much better and faster in Group B compared to Group A. Pain score less than 3 was achieved in Group B by 4th week, and in group A by 6th week. The average pain scores were 0.55 in Group B and 2.24 in Group A, indicating that utmost pain relief was better in Group B. The total percentage of pain recovery was 84% in Group A, which is comparable with the literature(Table6.3).

Study	Final Pain Score	Recovery With Diltiazem
Madhusudhan M. et al 2014	-	89.4%
Rajavaithyanathan et al 2015	3.38	-
Giridhar C. M et al 2014	-	78.26%
PRESENT STUDY	**2.24**	**84%**

Table 6.3 Pain Recovery with 2 % Diltiazem

Recovery of Bleeding per Anum

The total recovery rate by the 10th week in group A was 87.78% and that of Group B was 98.92%. Not much of the studies give data regarding the recovery of bleeding per anum. The available literature suggests that the recovery of bleeding per anum is one of the earliest response to the treatment along with the Pain recovery (Table6.4). In our study the response was quicker in both groups. The cure of bleeding per anum was achieved by 2weeks in nearly 75% patients of both Groups, which is faster as compared to that achieved by Manjunath S Koteennavaret al.

Study	Early response time
Manjunath S Kotennavar et al 2012	3weeks
Present Study	**2 weeks**

Table 6.4 Recovery of Bleeding per rectum with diltiazem.

MORBIDITY OF THE TREATMENT [71-76]

I. Faecal Incontinence rate

Faecal incontinence was analyzed based on the duration and separately classified as Temporary (<10 weeks) and Permanent (>10weeks).

The Temporary incontinence was initially calculated to be in 2.22% patients of Group A and 29.03% patients in Group B. But, the permanent incontinence was nil in Group A and was about in 3.22% in Group B which correlates with the data available in the literature (Table6.5).

STUDY	2% Diltiazem	Surgical Sphincterotomy
Madhusudhan M. et al 2014	Nil	2.1%
Ansar Latif et al 2013	Nil	6%
Rithin Suvarna et al 2012	Nil	9.27%
Majid Aziz et al 2009	Nil	3.33%

Present Study	**Temporary- 2.22%** **Permanent- Nil**	**Temporary-29.03%** **Permanent- 3.22%**

Table 6.5 Faecal Incontinence Rate in Surgical and Diltiazem Groups

II. Headache

The headache was specifically associated with Group A and its incidence was much lower 6.7% than with that of Glyceryl trinitrate (67%) as reported by Rithin Suvarna et al.

STUDY	Incidence of Headache
Manjunath S Kotennavar et al 2012	5.71%
Rithin Suvarna et al 2012	5.49%
Present Study	**6.7%**

Table 6.6 Headache in Diltiazem group

III. Itching

15.6% patients of Group A experienced localized itching, which was higher than that reported by madhusudhan M et al(4.3%). But it was mostly temporary which lasted few minutes after application of the Ointment.

Study	Incidence of Itching
Madhusudhan M et al 2014	4.3%
Present Study	**15.6%**

Table 6.7 Incidence of Itching in Diltiazem group

IV. Post-operative Pain, Surgical Site Bleeding & Infection

In Gorup B the specific drawbacks were Post-operative pain (43.01%), Surgical site bleeding (22.58%) & Infection (3.23%).

Study	Infection Rate
Rajan Vaithianathan et al 2015	4.44%
Present Study	**3.23%**

Table 6.8 Infection rate in Surgical group.

Recurrence Rate [71-76]

In the present study the recurrence rate in Group A (2% Diltiazem) was 6.67%, whereas it was nil with surgical method. The recurrence rate in the current Study was much lower than that reported in the literature. The data suggests Chemical sphincterotomy can definitively be used as an alternative to surgery when used with proper methodology and compliance.

Study	Recurrence rate
Nelson et al. 2012	12.5%
Abd Elhady et al. 2009	65%
Samim et al. 2012	17.6%
Suvarna et al. 2012	10.43%
Cevik et al. 2011	11.1%

Study	Recurrence rate
Madhusudhan M et al 2014	2.1%
Ansar Latif et al 2013	25%
Rithin Suvarna et al 2012	10.43%
Present Study	**6.67%**

Table 6.9 Recurrence Rate in Diltiazem Groups

The final draft drawn from these observations was that the Chemical Sphincterotomy using 2% Diltiazem has better side effect profile and good comparable healing rates in the treatment of symptomatic Chronic Anal Fissures. The drawbacks that warrant patient interest are the slower response, longer duration of treatment and more chances of recurrence. With view of all these parameters, it could be recommended that 2% Topical Diltiazem is the best available alternative for Surgical method in treatment of chronic fissure in ano.. And surgery can be reserved for Non-responders alone.

SUMMARY

The current study was an interventional study which compared the Chemical Sphincterotomy (using 2% Topical Diltiazem gel) with operative Surgical Sphincterotomy (Lateral Internal Sphincterotomy). The sample was selected from the population with specific Inclusion & Exclusion criteria. The total sample size was 190 of which 7 were dropouts. So only 183 patients were studied in this trial among which 90 belonged to Group A (Chemical Sphincterotomy) and 93 belonged to Group B (Lateral Anal Sphincterotomy). The following parameters were compared between the two groups.

- Fissure Healing Rate
- Pain Recovery Rate
- Bleeding per Anum Recovery Rate
- Work Resume Time
- Morbidity of the Treatment
- Faecal incontinence
- Recovery Time
- Recurrence Rate
- Conversion Rate

The study was done in Tirunelveli Medical College Hospital between March 2017 to September 2018.

The Conclusion drawn are below **Fissure Healing Rate:**

The final cure rates at 10th week for both the Groups were 84.4% in Chemical sphincterotomy and 97.85% in lateral anal sphincterotomy. The complete resolution of Fissure was documented from 4th week in both the Groups. The Surgical sphincterotomy had better healing than the Chemical method which was also statistically very significant.

Pain Recovery Rate:

The pain recovery was evident from the 2nd week in both the groups with the initial pain being halved. The final pain score by 10th week in Group A (chemical Sphincterotomy) was 2.24, which was acceptable, whereas in Group B (Surgical sphincterotomy) the final pain average was 0.55 (very negligible) showing complete resolution of symptoms. The rate of recovery was also quicker in Group B than Group A.

Bleeding Per Anum Recovery Rate:

The recovery of patients from Bleeding per anum also occurred earlier during the treatment by 2nd week in both the groups. The final recovery rates by 10th week were 87.78% in Group A and 98.92% in Group B, which correlates with Fissure healing rates.

Work Resume Time:

The average work resuming time were 3.37 weeks in Group A (Chemical Sphincterotomy) and 3.19 weeks in Group B which correlated best with the recovery of Pain and Bleeding per anum. The work resuming time was not statistically significant.

Recovery Time:

The recovery time shows the average Fissure Healing time. It was quicker in group B (Surgical Sphincterotomy) with about 4.84 weeks as its average recovery time while it was 5.18 weeks with Group A (Chemical sphincterotomy).

Morbidity of Treatment

The drawbacks unique to their respective groups. Group A had headache (6.7%) and itching (15.6%) as its unique side effects. Group B patients had Post-Operative Pain (43.01%), surgical site bleeding (22.58%) and Surgical site infections (3.23%).

Faecal incontinence

Faecal incontinence was mostly experienced by the Group B (Surgical sphincterotomy) patients in about 29.03% of them. Whereas it was only 2.22% in Group A Patients (Chemical Sphincterotomy), that too only temporarily. Out of the 27 patients only 3 had permanent incontinence.

Recurrence Rate & Conversion Rate

There was nil recurrence in Surgical limb (Group B) re- establishing that it is the Gold Standard in the treatment of Chronic fissure in ano. In group A (chemical Limb) the recurrence rate was 6.67%.

The conversion rate was about 16.67% in Group A and 2.15% in group B reflecting that failure rates were higher in Group A so that patients needed to shift to the Gold standard treatment.

The final inference from the study was that Group B (Surgical sphincterotomy) patients definitely had better recovery & response to the treatment than the Group A (Chemical Sphincterotomy) patients. The only notable major drawback was the higher faecal incontinence rate in Group B. On the other hand Group A patients also had significantly good recovery and response to the Chemical sphincterotomy method with lesser morbidity.

CONCLUSION

In present study it was observed that Chemical sphincterotomy with 2% Topical Diltiazem in the management of Chronic anal fissure in comparison with surgical sphincterotomy has: -

- Significant fissure healing rate
- Early recovery from bleeding per anum and pain with quicker recovery time
- Least side effect profile including risk of faecal incontinence
- Significant recurrence rate requiring surgical modality for non-responders.
- Needs proper patient education, motivation and compliance

Hence this study concludes that Chemical Sphincterotomy using 2% Topical Diltiazem could be used as a preliminary mode of management in treating chronic anal fissure before resorting the patients to Lateral Anal Sphincterotomy which must be used for patients who doesn't benefit from Chemical Sphincterotomy.

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PROFORMA

Patient Details

Name: *Age/Sex:* *IP/OP. NO.:*

Address: *Occupation:* *Mobile No:* **Complaints**

Chief complaints	*Duration*
Pain	
Bleeding Per Rectum	
Constipation	
Pruritis	

History

Nourishment	*Anaemic*	*Icteric*	*Cyanosed*	*Clubbing*	*Pedal edema*	*Pulse*	*B.P*	*Temp*	*Wt*

Inspection	*Fissure site*	*Number*	*Sentinel Pile*	*Discharge*	*Fistulous opening*
Sim's position					

Palpation	*Tenderness*	*Anal Tone*	*induration*	*Discharge*

Proctoscopy	*Anal mucosa*	*Hemorrhoids*	*Internal opening*

CARDIOVASCULAR SYSTEM

RESPIRATORY SYSTEM

ABDOMEN

CENTRAL NERVOUS SYSTEM

Past History	*Yes/no*	*Personal History*	
Tuberculosis		*Diet*	*High/low fiber*
Inflammatory Bowel Disease		*Fluid intake*	*>1.5/<1 l per day*
Previous Perianal surgeries		*Alcoholic*	*Yes/no*
Pregnancy		*smoker*	*Yes/no*
Cardiovascular Diseases		*Bowel habits*	*Regular/ irregular*

DIAGNOSIS

Investigations

Hb: *RFT:* *RBS:* *CXR: ECG:*

Management plan

High fiber diet Plenty of oral fluids Laxatives
Sitz bath

A

Chemical Sphincterotomy with 2% diltiazem,

B

Surgical Sphincterotomy with Lateral internal sphincterotomy

Timeline	*Pain score**	*Bleeding PR*	*Healing of the Fissure*	*Incontinence score***	*Recurrence*
2nd week					
4th week					
6th week					
8th week					
10th week					

SUCCESS	FAILURE	RECURRENCE	SWITCH OVER A B

INFORMED CONENT

I, Dr.V. Dheenadhayalan Post graduate student in Department of General Surgery conducting a dissertation work for award of MS degree in General Surgery.

The topic for the study **is "**A Comparative Study of Chemical Sphincterotomy (Using 2% Diltiazem) And Lateral Internal Sphincterotomy for Chronic Fissure In Ano**."**

Objectives:

1. To assess and compare the efficacy and morbidity of topical application of 2% diltiazem gel with that of Lateral internal sphincterotomy in patients diagnosed with chronic anal fissure.

I, have been told in a language that I understand ( ) about the study. I have been told that this is for a dissertation procedure, that my participation is voluntary and I he/she reserve the full right to withdraw from the study at my own initiative at any time, without having to give any reason, and that decision to participate or withdraw from the study at any stage will not prejudice my/his/her, rights and welfare. Confidentiality will be maintained and only be shared for academic purposes.

I hereby give consent to participate in the above study. I am also aware that I can withdraw this consent at any later date, if I wish to. This consent form being signed voluntarily indicates agreement to participate in the study, until I decide otherwise. I understand that I will receive a signed and dated copy of this form.

I have signed this consent form, before my participation in this study.

Signature of the subject:

Date:
Place:

Signature of the witness:
Date:

Place:

I hereby state that the study procedures were explained in detail and all questions were fully and clearly answered to the above mentioned participant /his/her relative.

Investigators signature:
Date:
Place:

Contacts address:

நோயாளிகளுக்கு அறிவிப்பு மற்றும் ஒப்புதல் படிவம் (மருத்துவ ஆய்வில் பங்கேற்பத்திற்கு)

ஆய்வு செய்யப்படும் தலைப்பு:

பங்கு பெறுவரின் பெயர்:

பங்கு பெறுவரின் வயது:

		பங்கு பெறுவர் இதனை ✓ குறிக்கவும்
1.	நான் மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்களை படித்து புரிந்து கொண்டேன். என்னுடைய சந்தேகங்களை கேட்கவும், அதற்கான தகுந்த விளக்கங்களை பெறவும் வாய்ப்பளிக்கப்பட்டுள்ளது என அறிந்து கொண்டேன்.	☐
2.	நான் இவ்வாய்வில் தன்னிச்சையாக தான் பங்கேற்கிறேன். எந்த காரணத்தினாலோ எந்த கட்டத்திலும், எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகி கொள்ளலாம் என்றும் அறிந்து கொண்டேன்.	☐
3.	இந்த ஆய்வு சம்பந்தமாகவோ, இதை சார்ந்து மேலும் ஆய்வு மேற்காள்ளும் போதும் இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். நான் ஆய்வில் இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன்.	☐
4.	இந்த ஆய்வின் மூலம் கிடைக்கும் தகவலையோ, முடிவையோ பயன்படுத்திக் கொள்ள மறுக்க மாட்டேன்.	☐
5.	இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக் கொள்கிறேன் எனக்கு கொடுக்கப்பட்ட அறிவுரைகளின் படி நடந்து கொள்வதுடன், ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்று உறுதியளிக்கிறேன். என் உடல் நலம் பாதிக்கப்பட்டாலோ, அல்லது எதிர்பாராத, வழக்கத்திற்கு மாறான நோய்குறி தென்பட்டாலோ உடனே இதை மருத்துவ அணியிடம் தெரிவிப்பேன் என உறுதி அளிக்கிறேன்.	☐

பங்கேற்பவரின் கையொப்பம் / ..... இடம்.....

கட்டைவிரல் ரேகை

பங்கேற்பவரின் பெயர் மற்றும் விலாசம் .....

ஆய்வாளரின் கையொப்பம் /..... இடம் .....

ஆய்வாளரின் பெயர் .....

மையம் .....

கல்வியறிவு இல்லாதவற்கு (கைரேகை வைத்தவர்களுக்கு) இது அவசியம் தேவை

சாட்சியின் கையொப்பம் /..... இடம் .....

பெயர் மற்றும் விலாசம் .....

KEY TO MASTER CHART

FISSURE LOCATION

A-ANTERIOR P-POSTERIOR

A+P- ANTERIOR &POSTERIOR

IMMEDIATE POST PROCEDURE COMPLICATIONS P- PAIN

I- SURGICAL SITE INFECTION B-SURGICAL SITE BLEEDING IT-ITCHING

H-HEADACHE

BLEEDING PER ANUM 0-NIL

1- OCCASIONAL BLOOD SPOTTING IN STOOLS(MINIMAL)

2- BLOOD STAINED STOOLS(MILD)

3- FRANK BLOOD IN STOOLS(MODERATE)

4- BLOOD CLOTS PASSING PER RECTUM(SEVERE)

COLOR CODING

	GROUP A
	GROUP B
	GROUP A FAILURES
	GROUP B FAILURES
	DROPOUTS
	RECURRENCE

S. No	Study No	Name	Age	Sex	Op No	2nd week	4th week	6th week	8th week	10th week
1	1	Subbulakshmi	25	F	107318		+			
2	3	Gandinathan	26	M	149723			+		
3	5	Mariammal	28	F	124568			+		
4	7	Muthumari	18	F	235461		DO			
5	9	Stephen Joseph	55	M	194732		+			
6	11	Gandimathi	25	F	139741			+		
7	13	Kalyanalakshmi	29	F	132654			+		
8	15	Ishwariya	30	F	179211		+			
9	17	Jayakumar	19	M	125678			+		
10	19	Subbiah	32	M	124567		+			
11	21	Padma	34	F	135621			+		
12	23	Valliammal	36	F	169875		+			
13	25	Ellupandian	16	M	145863				+	
14	27	Jayalakshmi	28	F	124785		+		DO	
15	29	karruppusamy	29	M	169874			+		
16	31	Thangammal	64	F	123569					
17	33	Karthik	17	M	124569		+			
18	35	Rohini	36	F	157893			+		
19	37	Jeenesh	55	M	136542		+			
20	39	Annamuthu	22	F	125879			+		
21	41	Krithika	32	F	125698				+	
22	43	Essakiammal	56	F	125689		+			
23	45	Gayathri	34	F	126547			+		
24	47	Sudalaimuthu	25	M	123654		+			
25	49	Chandra	28	F	132465		+			
26	51	Maari	58	F	198756				+	
27	53	Ramakrishnan	29	M	163978			+		
28	55	Kaaliammal	24	F	145689					
29	57	Essakiammal	25	F	195462		+			
30	59	Mallika	59	F	132685			+		
31	61	Rani	32	F	136574				+	
32	63	kannan	17	M	132695		+			
33	65	Vellasamy	34	M	165478					
34	67	Manimegalai	62	F	165985			DO		
35	69	lakshmi Devi	64	F	126475		+			
36	71	Govindan	36	M	163254			+		
37	73	Kalavathy	19	F	125469		+			
38	75	Chidambarakani	38	F	132659			+		
39	77	Petchi	39	F	123647					
40	79	Rajendran	62	M	159846		+			
41	81	Natchiyar	63	F	123652			+		
42	83	Kupliyaandi	42	M	168745			+		
43	85	Muthukani	44	F	136598		+			
44	87	Rajagopal	61	M	164253		+			
45	89	Vellamal	45	F	145623			+		
46	91	Muthusamy	60	M	165324		+			
47	93	Arputhamary	25	F	148659			+		
48	95	Vadivu	46	F	136528		+			
49	97	Muthupandi	48	M	175469				+	
50	99	Balasurya	55	F	165234			+		
51	101	Rajeshwari	28	F	165892					
52	103	Balakrishnan	56	M	132456		+			
53	105	Monisha	50	F	187542			+		
54	107	Balamurugan	57	M	165234		+			
55	109	Kaalimuthu	45	M	165289			+		
56	111	Chelladurai	46	M	167542					
57	113	Muthuraj	58	M	169857		+			
58	115	Vijayakumar	29	M	123657					DO
59	117	Anthonyraj	24	M	156987			+		
60	119	Karunakaran	59	M	136528		+			
61	121	Gopalasamy	36	M	184573		+			
62	123	Suresh	38	M	136952			+		

63	125	Palani	62	M	245876			✚		
64	127	Paapa	36	F	136529					
65	129	Periyadevar	61	M	145328		✚			
66	131	Ganeshan	39	M	169875			✚		
67	133	Ramasamy	37	M	125476				✚	
68	135	Muneeshwaran	63	M	165329		✚			
69	137	Chellapandi	19	M	156498			✚		
70	139	Paramsivam	42	M	123478			✚		
71	141	Muthuiah	45	M	159623		✚			
72	143	Jayaraj	64	M	175489					
73	145	Sivalingam	44	M	163285		✚			
74	147	Kumar	46	M	169754		✚			
75	149	Muthuselvan	59	M	125478	DO				
76	151	Saravanan	48	M	123578					
77	153	Padmanaban	58	M	184597		✚			
78	155	Mydeen	29	M	126354			✚		
79	157	Baskar	30	M	128569		✚			
80	159	Pandian	20	M	136745					
81	161	Essakiappan	32	M	132569			✚		
82	163	Muthuraj	33	M	175486					
83	165	Bharanidharan	38	M	169875					
84	167	Muthu	64	M	163257		✚			
85	169	Arun	29	M	185479					
86	171	Chandru	26	M	123685		✚			
87	173	Kalai	33	M	175489					
88	175	Bharathi	39	M	169852			✚		
89	177	Diwahar	50	M	167548		✚			
90	179	Jason	64	M	163258					
91	181	Rajesh	46	M	159872			✚		
92	183	Essakimuthu	43	M	157426		✚			
93	185	Mariappan	59	M	136582		✚			
94	187	Vinoth	49	M	147865			✚		
95	189	Raju	29	M	132659		✚			

S. No	Study No	Name	Age	Sex	IP No	2nd week	4th week	6th week	8th week	10th week
1	2	Naseer begam	52	F	32625		+			
2	4	Ramasamy	26	M	30862		+			
3	6	Indra	18	F	30788			+		
4	8	Marimuthu	58	M	83301		+			
5	10	Lakshmi	30	F	32521			+		
6	12	Gajendran	59	M	32570		+			
7	14	Thangaraj	23	M	32625			+		
8	16	Chellammal	32	F	32550		+			
9	18	Subbuammal	64	F	73551			+		
10	20	Iyyappan	35	M	34547		+			
11	22	Vadivu	17	F	35679		+			
12	24	Thangapushpam	36	F	37451			+		
13	26	Perrachi	35	M	38925		+			
14	28	Thangammal	16	F	38923		DO			
15	30	Tamilselvi	56	F	40729		+			
16	32	Muthuammal	39	F	42416			+		
17	34	Padmavathy	54	F	45476			+		
18	36	Kumar	22	M	52553		+			
19	38	Tamilarasi	40	F	54445		+			
20	40	Vijayalakshmi	59	F	54419			+		
21	42	Gurunathan	42	M	54564				+	
22	44	Kumari	62	F	57463		+			
23	46	Madasamy	44	M	55881		+			
24	48	Radha	64	F	59179		+			
25	50	Das	25	M	59274			+		
26	52	Navinraj	26	M	64349		+			
27	54	Fathima	28	F	74490				+	
28	56	Nellaippan	32	M	70655		+			
29	58	Michael	33	M	70572			+		
30	60	George	20	M	73985		+			
31	62	Subbulakshmi	36	F	23506			+		
32	64	Rohit	50	M	77703					
33	66	Annie	18	F	31341		+			
34	68	Kaaliappan	45	M	21616					
35	70	Sivaperumal	56	M	29839		+			
36	72	Ganesan	49	M	35877			+		
37	74	Poolammal	45	F	34456		+			
38	76	Muthulakshmi	19	F	40445		+			
39	78	Arunachalam	42	M	60655			+		
40	80	Gnanaprakash	28	M	61635		+			
41	82	Thirumalai	16	M	43611			+		
42	84	Anitha	26	F	6557		+			
43	86	Vellammal	55	F	37609		+			
44	88	Sekar	25	M	65407		+			
45	90	Murugeshwari	22	F	67359			+		
46	92	Marimuthu	30	M	3682		+			
47	94	Rubi	54	F	9006		+			
48	96	Ganesh Kumar	24	M	4064		+			
49	98	Saraswathi	32	F	6136			+		
50	100	Paulraj	33	M	67090		+			
51	102	Samuthirakani	57	F	70058			+		
52	104	Sheik mohammed	39	M	68842			+		
53	106	Amutha	64	F	60791		+			
54	108	Shanmugavel	35	M	72222		+			
55	110	Venkatesh	62	M	7371111			+		
56	112	Selvakumar	42	M	76328		+			
57	114	Shobana	45	F	777784		+			
58	116	Essaki	46	M	6151		+			
59	118	Shanmugam	48	M	7778			+		
60	120	Mymoon Beevi	64	F	7931		+			
61	122	Rama	46	F	67767				+	
62	124	Vishal	48	M	12985		+			

63	126	Kaalimuthu	47	M	16127			✚		
64	128	Selvi	63	F	16153		✚			
65	130	Roja	49	F	17966			✚		
66	132	Shankaralingam	28	M	19496		✚			
67	134	Chokanathan	29	M	19482		✚			
68	136	Vellapandi	30	M	17911			✚		
69	138	Chellathai	19	F	2274		✚			
70	140	Petchiammal	35	F	23031			✚		
71	142	Muthuraj	36	M	24140		✚			
72	144	Baseer	32	M	21226		✚			
73	146	Veerammal	31	F	24700			✚		
74	148	Essakiammal	30	F	23025		✚			
75	150	Subramani	38	M	26268			✚		
76	152	Ambika	39	F	26300			✚		
77	154	Uthira	62	F	28252		✚			
78	156	Umayun	40	M	28134		✚			
79	158	Velselvi	45	F	79243			DO		
80	160	Santhoshi	23	F	28098		✚			
81	162	Muppidathy	46	F	29682			✚		
82	164	Arokiyam	61	F	29770		✚			
83	166	Arjun	45	M	31391			✚		
84	168	Divya	61	F	31466		✚			
85	170	Tamilarasan	24	M	33307			✚		
86	172	Mariyapushpam	42	F	33450		✚			
87	174	Krishnammal	64	F	32108			✚		
88	176	Amravathi	41	F	33346		✚			
89	178	Rajeshwari	35	F	37245			✚		
90	180	Thulasi	64	F	37072		✚			
91	182	Oorkali	33	F	31308		✚			
92	184	Arumugam	62	M	37320			✚		
93	186	Essakiammal	36	F	35061		✚			
94	188	Shanthammal	39	F	38819			✚		
95	190	Shanthi	61	F	38816		✚			